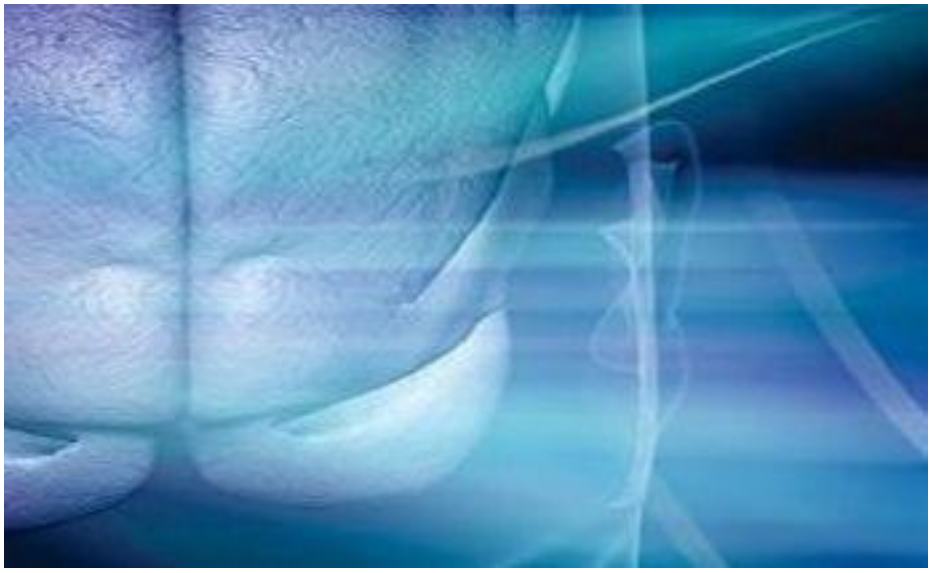

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INSTRUCTIONS FOR AUTHORS

Papers submitted should be original documentation, including photographs. The papers should be single column, double-spaced. The title should be in title case and bold, followed by Authors, degree, organization and city, state.

The papers should contain an abstract and be separated into sections with bold typing of the section title. The page set-up should be 0-6.5 inches. Paragraphs should be indented 0.5 inches. All tables should be submitted separate from the paper. If possible make the tables up to 3 inches wide so that they could fit into a column. This will allow quicker scanning and preparation.

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EDITOR'S PAGE

Physicians in training, learn and practice research "To formulate, ingrain, and measure, a method of thought, investigation, and evaluation necessary for physicians to have multi-lateral information exchange and communication with experts in areas of scientific and medical discovery, knowledge, and analysis, in order to continuously and efficiently improve human health and patient care." Understanding and performing quality research provides students and residents the tools to propel quality medical care into the community and into the future.

Welcome to the Journal of the American Organization of Neurological Surgeons and the American College of Osteopathic Surgeons Neurosurgical Section. This volume is composed of the Residents' annual papers that were submitted but not published elsewhere. It is therefore dedicated to the future Neurosurgeons and their education. All papers were reviewed by the peer review committee and selected for awards. The papers submitted are excellent, representing some of our talented colleagues. Issues will be published annually. I hope that this issue will spread the knowledge of our residents and our section. We will continue to solicit annual papers and all papers submitted at the annual meeting. This is your Journal paid for by your annual dues. This issue is available on our website AOANeurosurgery.org. This is your organization; please support it as you can.

Thank you,

Dan Miulli, D.O, F.A.C.O.S
Editor

2013 Annual Resident Paper Winners

1st Place Jason Dreyer, DO - Providence: Randomized, blinded, sham-controlled trial of thoracic and pedal pump techniques in patient with intracranial pressure monitors. Award $1500

2nd Place Mark Rivkin, DO - PCOM: Effects of Body Mass Index on Adverse Perioperative Events in Patients Undergoing Elective Lumbar Fusion. Award $1000

3rd Place Bryan Bolinger, DO - PCOM:Comparison of O-Arm vs. Fluoronav Image Guided Lumbar Pedicle Screw Placement: A Single Institutions Experience. Award $500

All Residents will be expected to be at the ACA November 14-17 in Las Vegas for the 1st Day of Presentation to give a 10 minute talk about their research.

Randomized, blinded, sham-controlled trial of thoracic and pedal pump techniques in patient with intracranial pressure monitors

Jason Dreyer, DO[1]; Kenneth D'Andrea, DO[1]; Stephanie Falatko, DO[1]; Pradeep Setty, DO[1]; Ryan Barrett, DO[2]

Abstract

Context

Osteopathic manipulative treatment (OMT) can be used as primary or adjuvant treatment to manage conditions throughout the body. The use of OMT to treat intracranial hypertension has been rarely reported. The objective of this randomized, blinded, sham-controlled study is to assess whether daily treatments with the thoracic and pedal pump techniques decrease intracranial pressure (ICP) in patients with ICP monitors.

Methods

This randomized, blinded, sham-controlled study was conducted at one institution between July 1, 2011 and June 30, 2012. Informed written consent was obtained from every patient or their legally authorized representative. Institutional Review Board (IRB) approval was obtained. Patients had an ICP monitor placed by the neurosurgical service for a variety of reasons. Pedal and thoracic pump tenchiques, or sham treatment, was performed on a daily basis. Pretreatment and post-treatment ICP and cerebral perfusion pressure (CPP) were recorded. Other data collected included: hourly ICP, hourly CPP, hourly blood pressure (BP), daily Glasgow Coma Scale (GCS) and white blood cell count, daily chest X-ray results, length of ICP monitor use, need for permanent cerebrospinal fluid (CSF) diversion, Glasgow Outcome Scale (GOS) at discharge, site of infection (if applicable), antibiotic usage (days and type), days of ventilator use, diagnosis, and length of stay.

Results

Forty-two patients had ICP monitors placed at our institution from July 1, 2011 to June 30, 2012. Differences between patient gender, age, or incoming GCS among the treatment, sham, or refused-consent group were not statistically significant. No primary and secondary outcome measure reached statistical significance, although there was a positive trend in the OMT treatment arm across most outcome measures. OMT did not adversely affect ICP or CPP.

Conclusion

The pedal pump and thoracic pump techniques can be safely performed on patients with neurologic disease necessitating an ICP monitor. There were no statistically significant primary or secondary outcome measures, although most trended towards more favorable outcomes in patients treated with OMT.

Introduction

Osteopathic manipulative treatment (OMT) can be used as primary or adjuvant treatment to manage conditions throughout the body.[1] In children with recurrent acute otitis media, OMT and antibiotics significantly reduced repeated episodes and need for tympanoplasty tube insertion compared to antibiotics alone.[2] The New England Journal of Medicine reported OMT and standard care have similar results treating patients with low back pain, but OMT patients required significantly less medication.[3] With respect to inpatient care, OMT has been reported to significantly shorten antibiotic use and length of stay in elderly patients with pneumonia.[4]

Intracranial pressure (ICP) is simply the pressure within the skull. Measuring ICP can be important in patients with head injury, tumors, stroke, venous thrombosis, etc. There is higher mortality and worse outcome in patients with ICP persistently greater than 20mmHg.[5] The use of OMT to treat intracranial hypertension has been rarely reported. A recent study demonstrated the safety of two specific OMT techniques – the thoracic pump and pedal pump – in patients who suffered traumatic brain injuries.[6] In that study, patients tolerated the techniques well with trending decreases in intracranial pressure; however, changes were not statistically significant.

The rationale for use of the thoracic pump and pedal pump techniques in patients with intracranial pressure monitors is multifaceted. First, these techniques are designed to optimize lymphatic circulation. Theoretically, interstitial fluid within the brain will be reabsorbed and circulated away, thereby lowering ICP. Second, two tenets of osteopathy are: the body is self-healing and self-regulating, and structure and function are interrelated. Therefore, by restoring optimal body-structure, optimal somatic function will be achieved. Third, cerebrospinal fluid (CSF) absorption occurs via arachnoid villi and lymphatics. These OMT techniques may help to optimize lymphatic absorption, as well as, pressure-dependent absorption of CSF by the arachnoid villi.

The objective of this randomized, blinded, sham-controlled study is to assess whether daily treatments with the thoracic and pedal pump techniques decrease ICP in patients with intracranial pressure monitors. In addition to ICP, other objective data primarily collected include: cerebral perfusion pressure (CPP), daily Glasgow Coma Scale (GCS), days of ICP monitor use, and need for permanent CSF diversion. Secondary outcome measures include: length of intensive care unit (ICU) stay, days of ventilator-dependence (if applicable), daily white blood cell (WBC) count, source of infection (if applicable), and length of antibiotic use (if applicable).

Methods

This randomized, blinded, sham-controlled study was conducted at one institution between July 1, 2011 and June 30, 2012. Inclusion criteria were patients 18 years and older who had abnormal computerized tomography (CT) scan of the head or unexplained decline in level of consciousness requiring insertion of an ICP monitor. Postoperative patients with ICP monitors were also included. Patients under the age of 18 years, greater than 3 consecutive rib fractures, presence of a chest tube, lower extremity fractures, and/or unstable spine fractures were excluded due to contraindication of OMT.

Informed written consent was obtained from every patient or their legally authorized representative prior to any study treatments being performed. Neurosurgery attending physicians were contacted for consent to have their patients participate in the study. Institutional Review Board (IRB) approval was obtained.

Patients had an intracranial pressure monitor placed by the neurosurgerical service for a variety of reasons, which have been previously listed. This occurred in the emergency department, intensive care unit, or operating department. Within twenty-four hours of the monitor placement, a representative from the research team attempted to recruit, consent, and enroll the patient into the study. This often involved obtaining consent from the patient's legally authorized representative. Patients who were outside the twenty-four hour window or who refused enrollment had their data collected for a comparison group.

Once enrolled, the research team randomized patients to either therapeutic or sham treatment using a true random number generator at random.org. The primary investigator and nontreating members of the research team were blinded to treatment arms.

After enrolling a patient, the treating physicians conducted either OMT or sham treatment for each study patient on a daily basis. The treating physicians were first or second-year docors of osteopathy (DO) neurosurgery residents who received additional training in the pedal pump and thoracic pump techniques.

For treatment, the patient remained supine with the head of their bed elevated to 30 degrees. Pretreatment ICP and blood pressure (BP) were documented. The physician stood at the patient's feet and performed either the pedal pump technique or sham (hands-on) for one minute. ICP was recorded during a one minute pause. The technique or sham was repeated two more times. ICP was recorded during the one minute pauses. Any CSF output was also recorded. The physician moved to the patient's head taking care to avoid all lines, monitors, and tubes. The thoracic pump technique or sham was performed for one minute. ICP was recorded during a one minute pause. The technique or sham was repeated two more times. ICP was recorded during the one minute pauses. Any CSF output was again recorded.

After therapy, the treating physician recoded treatment data in the database. Other data collected included: hourly ICP, hourly CPP, hourly BP, daily GCS and white blood cell count, daily chest X-ray results, length of ICP monitor use, need for permanent CSF diversion, Glasgow outcome scale (GOS) at discharge, site of infection (if applicable), antibiotic usage (days and type), days ventilator use, diagnosis, admission date, discharge date, and date of birth.

Patient randomization and treatment was blinded to the primary investigator and the rest of the research team. Database access with respect to randomization arm was restricted to the primary investigator and the research team until the end of the study. The intensive care unit nurses were asked not to discuss the treatments witnessed.

Data was analysed using averages, standard deviations, and the student t-test. The randomized treatment arm was compared to both the randomized sham treatment arm and the group of

patients who refused consent when applicable. The later group did not have OMT or sham, but their secondary outcome measure data was prospectively collected. This served as a second control. The predetermided significance level for the student t-test was a p-value less than 0.05.

Results

Forty-two patients had ICP monitors placed at our institution from July 1, 2011 to June 30, 2012. Twenty-six patients were not enrolled in the study because of refusal to participate. Sixteen patients were enrolled and randomized to treatment or sham therapy. Patient characteristics are displayed in table 1. Patients randomised to the treatment-arm had a worse average incoming GCS, but not to a statistically significant extent. Differences between patient gender, age, or incoming GCS among the treatment, sham, or refused-consent group were not statistically significant.

The nine patients randomized to the treatment-arm recieved a total of thirty-six OMT sessions. Sham treatment was conducted a total of twenty-four times on the seven patients randomized to the control-arm.

Primary and secondary outcome measures are listed in table 2 along with standard deviations and applicable statistics. None of the measures reached statistical significance, although there was a positive trend across all outcome measures (fewer days with the ICP monitor, ventilator days, days with infection, days of pathologic chest x-ray, days of antibiotic use, days where medical management was required to control elevated ICP, total days in the ICU, and better GOS), except leukocytosis days (days with WBC > 12,000 cells/mcL).

Enrolled patients had one hundered eighteen patienr-hours of ICP and CPP recorded. Patient who refused treatment had One hundered eighty seven-hours of ICP and CPP recorded. No statistical sigificance in ICP or CPP was found between treatment and sham or treatment and refused-consent group.

There were no adverse reactions to the OMT. Baseline ICP and CPP were compared to those after pedal pump and thoracic pump treatment and sham. ICP did decrease on after OMT, but it also decreased in the sham group. There was no statistical significance between those data. They are summarised in table 3.

Overall there were no statistically significant findings among primary or secondary outcome measures. Most trends were toward more favorable outcomes. OMT did not adversely affect ICP or CPP.

Comment

OMT is an importnat and effective treatment for many conditions suffered by critically ill patients.[4] Unfortunately, OMT is often withheld from patients with intracranial disease. The concern is that certain teqhniques may increase the ICP of this patient population.

The pedal pump and thoracic pump techniques were recently studied in patient with traumatic brain injury.[6] These patients had slight decreases in ICP and increases in CPP, but the data did not reach a statistically significant threshhold.

The present study again demonstrates that the pedal pump and thoracic pump tenchiques may be utilized across patients with a spectrum of intracranial disease. There were no statistically significant results among primary and secondary outcome measures, althouh most trended toward a more favorable outcome. This is particularily of note in light of the fact that the average incoming GCS in the treatment group was worse than the sham group (although not to a significant extent). As with the prior study, there were slight decreases in ICP in treated patients from baseline, but this did not acheive statisticaly significance. There were no adverve outcomes to patients resulting from the OMT.

This study was limited in its number of enrolled patients. Less than half of the patients or their representitives agreed to participate. There were many self-imposed and IRB-imposed criteria that required strict adherence, such as: enrollment within twenty-four hours of ICP monitor placement, in-person signing of the consent (as opposed to phone consent), use of translation service when applicable, etc. It seemed that patient representatives had a difficult time consenting for a randomized study when they were already going through the stress of the patients' admitting diagnosis. Additionally, over the year of enrollment, there were fewer ICP monitors placed than anticipated (forty-two). In the two preceeding years, there were seventy-six, and eighty-eight monitors placed.

The strength of this study was its randomized, sham-controlled, blinded nature. The treatment was administered by a group of specialty-trained, recently graduated doctors of osteopathic medicine. As the practice of medicine continues to rely on evidence-based outcome data, these types of studies will become more vital and relavent.

Future research with resepect to lymphatic techniques for ICP management might include an expasion of the current study with greater patient enrollment. Now that two studies have demonstrated no adverse events with these techniques, perhaps IRB exemptions to the consent process could be obtained, especially at primarily osteopathic hospitals where OMT is routinely performed. If this study would have enrolled sixty simillarily-randomised patients, a statistically significant Glasgow Outcome Scale would have been demonstrated. Many osteopathic ficilities that include a neurosurgical service-line could achieve that many patients within a year. Gathering and publishing these data is essential for the future of osteopathic neurosurgery.

Conclusion

The pedal pump and thoracic pump techniques can be safely performed on patients with neurologic disease necessitating an ICP monitor. There were no statistically significant primary or secondary outcome measures, although most trended towards more favorable outcomes.

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Effects of Body Mass Index on Adverse Perioperative Events in Patients Undergoing Elective Lumbar Fusion

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ABSTRACT

Background and Context: Low back pain is a widely prevalent condition affecting ion over 100 million adults in the US. Numerous surgical procedures for this problem are performed annually and carry an enormous price tag to the health care system. The financial burden is further amplified by patient-related factors that predispose to perioperative complications and greater costs. Body Mass Index (BMI) has recently been investigated as one such factor during lumbar fusion surgery. Unfortunately, there is paucity of literature on this topic.

Purpose: We set out to investigate the impact of BMI on the incidence of perioperative complications in an elective lumbar fusion surgery cohort performed for degenerative pathology in spinal surgery naïve population.

Study Design: Prospective, observational study at the same tertiary care center.

Methods: For ten consecutive months patients undergoing elective lumbar fusions were asked to volunteer. Prospective evaluation of perioperative complications between two body habitus groups (BMI≤<29.9 and BMI≥>30) was performed. Standard surgical and postoperative care was delivered to all patients. Every patient underwent an instrumented lumbar fusion.

Results: Forty-seven patients with mean age of 53.8 years old (range 29-72) volunteered for the study. Overall, 22 adverse events (17 minor and 5 major), occurred in 13 patients (46.1%). Minor and major complication rates were 36.1% and 10.8%, respectively. There were more minor (54% vs. 25%), major (21% vs. 12.5%), and total complications (73.6% vs 28.5%) in the obese group. When examining the major events independently, there is a strong trend toward seeing such complications in obese patients (p=0.08). The average per-patient complications rates were 0.29 and 0.74 favoring obese patients and reached statistical significance (p=0.029). Length of stay was 0.55 days greater in obese group and demonstrated a strong statistical trend (p=0.07).

Conclusion: Increasing BMI carries a risk of greater perioperative complications and longer length of stay when comparing obese to non-obese patients. Healthcare costs associated with

obesity as observed in this study should encourage spine surgeons to re-examine their patient selection criteria. Conservative management and weight loss may reduce symptomatic spinal disease and attenuate the need for spinal surgery.

Introduction

Back pain affects more than 80 percent of people and is associated with treatment related costs of more than $100 billion annually in the U.S.[1] Currently more than 650,000 surgical procedures for low back pain are performed each year in the country with costs exceeding $20 billion.[2] The economic burden is further amplified by medical costs associated with procedure-related complications in the immediate postoperative period as well as failure of symptomatic improvement leading to revision surgery. In fact, a recent report estimated the cost of revision lumbar surgery to be $32,915 ± $8344 per patient two years after the procedure.[3]

The incidence and types of adverse events associated with spinal surgery are well described in the literature. Interestingly, the authors also established a statistically significant difference between prospective and retrospective studies with increased incidence of adverse events discovered in prospective reports. While large retrospective MEDLINE review reported a complication incidence to be 16.4%, a recent prospective series documented the incidence of minor and complications to be 46.4% and 21.3%, respectively, for thoracolumbar procedures.[5]

Numerous studies in spinal literature attempted to correlate surgical outcomes with pre-operative comorbidities in order to elucidate patient-related variables associated with poor outcomes and higher complication rates.[6] Most recently, patients' size has received attention as a contributing factor association with post-operative complications.[5,7,8,9,10,11,12] BMI makes for an interesting target as it is estimated that 110 million Americans are either over-weight (Body Mass Index (BMI) 25.0 to 29.9) or obese (BMI ≥30).[13,14,15] Numerous technical challenges are correlated with elevated BMI in the surgical setting and include difficulty with positioning and imaging, venous and arterial access, perioperative airway management, and the use of lipophilic anesthetics.

Although the literature suggests a growing association between obesity and higher incidence of complication rates, no consensus has been reached in the spine community due to conflicting results from the few available trials. This is further confounded by a multitude of surgery-related variables reported in these studies such as instrumented and non-instrumented cases, both fusion and decompression procedures, as well as varying proportions of revision surgeries. This report attempts to prospectively investigate the association between BMI and perioperative complications while controlling for many procedure or pathology-related variables.

Patients and Methods

This study gained approval by the Institutional Review Board at Cooper University Hospital and is incompliance with HIPPA guidelines. This is a prospective, observational study conducted at Cooper University Hospital starting in September 4, 2012 and commencing on June 30th, 2013 with a total patient number of 47. All patients were consented the morning of surgery.

They received standard operative treatment and post operative care that is currently delivered for all elective lumbar fusion patients by the Department of Neurosurgery. No new interventions outside of the standard scope of practice were employed during the study. This investigation evaluated data collected only during the initial hospital stay for each patient.

The following inclusion criteria were utilized during this study: age ≥ 18, elective surgery, degenerative pathology, and lumbar fusion procedure as performed by the Department of Neurosurgery staff. Exclusion criteria were prior lumbar surgery, history of tumor, infection or trauma precipitating surgery, emergent procedures, and lumbar fractures. Adverse perioperative events occurring during the index hospitalization were recorded in a prospective manner.

All adverse events were available and retrievable through the electronic medical record system employed by the hospital. A total of 30 complications (15 minor and 15 major) were adopted from previously published report that defined complications in spinal procedures (Figure 1).

Figure 1: Previously validated adverse events

Major	Minor
DVT	Superficial wound infection
PE	Wound non healing
New/acute renal problem	Incidental durotomy
Pneumonia	Positioning-related palsy/injury
Prolonged intubation	Traumatic Foley insertion
New onset arrhythmia	Traumatic IV insertion
Deep wound infection/collection	Traumatic intubation
Hardware malposition	Narcotic withdrawal/oversedation
MI	Line infection
New neuro deficit	UTI
Sepsis	Lung atelectasis
Wrong level surgery	Postoperative fever
Pseudomeningocele	Ileus
Return to OR	Excessive EBL/transfusion
Death	Other medical complication

** Modified from Lebude et.al., Rattlif et. al. and Whitmore el.al* [32,33,34]

Additional data recorded included age, preoperative diagnosis (disc pathology, central stenosis, spondylolisthesis, degenerative scoliosis), gender, BMI, surgical levels, estimated surgical blood loss, operative duration, length of hospital stay, preoperative comorbidities. Patients' BMI was recorded in accordance with NIH definition of obesity (BMI$\geq$30).

Surgical Technique:

All procedures in the present study were performed by two senior Neurosurgeons at Cooper University Hospital using identical surgical approaches, intra-operative imaging, wound closure, and postoperative care. Upon signing informed consent for study participation, each patient was taken to the operating suite and administered general endotracheal anesthesia. A Foley catheter and anti-embolic stockings were placed and patients were positioned prone on the Jackson table. All appropriate pressure points received padding. A midline incision was marked depending on the level of pathology which was confirmed by fluoroscopic imaging. Patients were prepped and draped in sterile fashion. After making the incision, dissection was carried down in subperiosteal fashion to expose the lamina, facet joints, and transverse processes across all levels of interest. This was confirmed again with a lateral fluoroscopic intraoperative imaging. Once the exposure was completed, a laminectomy and foraminotomies were performed with Leksell rongeurs and a variety of Kerrison rongeurs. Once the decompression was completed, the O-Arm (Medtronic/Breakaway Imaging, Littleton, MA) was brought into the field to obtain images for placement of pedicle instrumentation. Using standard anatomic landmarks and the O-Arm images as an adjunct, pedicle screws were then placed. Two rods were then contoured to fit the screw heads. Locking caps were then placed and these were tightened down to the appropriate torque. Any areas of bone that were not decorticated already were then done so with a high-speed drill. The patient's own morselized bone and Trinity Evolution (Orthofix, Dallas, TX) was then placed in the lateral gutters along the transverse processes of interest. A 10-French JP drain was then placed to bulb suction. The wound was closed in standard facial layers. Prior to complete closure, 1 gram of Vancomycin powder was placed in the wound. Appropriate dressing was applied. The patient was then repositioned supine on the hospital bed and allowed to wake up from anesthesia. All patients were subsequently transferred to post-anesthesia recovery unit.

Statistical Analysis:

This study employed the Pearsons chi square test, Fisher test and Mann Whitney U test to compare all the major and minor adverse events across different BMI groups in search of statistical significance hereby defined as $p<.05$.

Results

Forty-seven patients with mean age of 53.8 years old (range 29-72) and mean BMI of 29.2 (range 19.5-45.7) were prospectively enrolled in the study between September 4, 2012 and June 30, 2013; there were 28 females (59.6%) and 19 males (40.4%). Patient cohort was subdivided into two categories for the purposes of statistical analysis, non-obese (BMI$\leq$ 29.9) versus obese (BMI $\geq$ 30). Nineteen patients (40.4%) were classified as obese with mean BMI of 34.3 while non-obese patients had a mean BMI of 25.7 ($p<.001$). The two groups were evenly matched as age, gender, mean number of surgical levels, as well as preoperative diagnosis did not reach statistical significance (Figure 2). Looking at peri-operative characteristics, we found no statistical differences in either surgical blood loss or operative duration between the two groups. However, a strong trend was identified in the length of stay with the obese population staying 0.55 days longer.

Figure 2. Demographics and surgical data for obese vs non obese patients

Mean / SD	**Obese**	**Non-Ob**	**P value**
Number of Pts	19	28	
BMI	34.3	25.7	<0.001
	3.89	2.75	
Age	54.47	52.43	0.65
	13.13	12.48	
Gender (M/F)	6m / 13f	13m / 15f	0.88
Surgical Levels	2.05	2.32	0.27
	0.9	1.3	
EBL	475	367	0.31
	320	221	
OR time	263	254	0.8
LOS	4.1	3.55	0.07
	2.29	1.28	

Four most common medical conditions in our patient cohort were hypertension, diabetes, obstructive airway disease (asthma, COPD), and hyperlipidemia. Strong trend or statistical significance was demonstrated in all conditions toward greater prevalence in obese patients (Figure 3).

Figure 3: Baseline medical conditions

Condition	Non Obese	Obese	P Value
HTN	9	9	0.06

DM	3	6	0.08
COPD/Asthma	3	8	0.01
Hyperlipid	6	10	0.05

We also examined the incidence of complications in the two groups. Overall, 22 adverse events (5 major [22.7%] and 17 minor [77.3%]) occurred in 13 patients (27.7%). Non-obese patients experienced 8 adverse events, 7 minor and 1 major (pneumonia), while obese patients demonstrated 14 adverse events, 10 minor and 4 major (sinus tachycardia, malpositioned screw into disc space, anemia requiring blood transfusion, return to OR for epidural hematoma with neurologic deficit). The average per-patient complications rates were 0.29 and 0.74 favoring obese patients and reached statistical significance (p=0.029). There were more minor (54% vs. 25%), major (21% vs. 12.5%), and total complications (73.6% vs 28.5%) in the obese group. When examining the major events independently, there is a strong trend toward seeing such complications in obese patients (p=0.08). Furthermore, 2 patients in the non-obese group and 5 patients in obese group experienced multiple complications (p=0.1).

Discussion

In patients undergoing elective lumbar fusion procedures the incidence of lumbar perioperative adverse events is poorly defined and highly contested in the literature. Much of this is attributed to the heterogeneity of spinal procedures and study designs used to evaluate this issue. The present study attempted to eliminate many confounding variables in hopes of defining a true complication incidence associated with body habitus.

Consequently, we focused on a single spinal procedure (instrumented decompression and fusion), and one anatomic region (the lumbar spine). We further reduced bias by excluding patients who had any prior surgical procedures in the lumbar region, even those who had a previous procedure at levels different than the targeted levels in the current study. Revision surgery is widely accepted as being technically challenging and associated with higher rates of adverse events in the published literature. We also focused only on degenerative pathology in order to include the vast majority of patients receiving surgery for chronic low back pain while excluding potential confounding variable such as history of trauma, tumor and infection from our cohort. Moreover, the two primary neurosurgeons performing these procedures (JDB, SSY) employed the same surgical techniques, used the image-guidance system, as well as the same surgical implant vendor. Lastly, there is evidence that retrospective reviews tend to underestimate adverse events in spinal surgery.[4,5,7] Therefore, we elected to investigate this issue prospectively. To our knowledge, this is the first and largest such series prospectively investigating the effect of BMI on perioperative complications in a naïve, degenerative lumbar fusion cohort.

The overall incidence of adverse events in present study was 46.1%; minor and major complication rates were 36.1% and 10.8%, respectively. These findings are consistent with previous reports. A recent MEDLINE review of spinal surgery focusing on incidence of complications in 79,471 patients reported an overall incidence of 16.4%.[4] The authors also reported a statistically significant difference among prospective and retrospective studies with increased incidence in prospective reports and exceeded 20% in prospective thoracolumbar reports.[4] A single center prospective trial of 248 patients reported even higher complication rates of 53.2% overall.[5] Minor complication incidence was 46.4% and a major complication incidence reached 21.3%.[7] Additionally, another single center prospective study of 128 patients reported that posterior thoracic and lumbar procedures were associated with 49.3% of patients who experienced at least one complication.[19]

While there was no statistical difference in operative blood loss and surgical times, the mean length of stay was 4.1 days for obese patients and 3.55 days for non-obese which confirmed a strong trend. Contrary to our findings, Rihn et. al. found that surgical time was higher in obese patients by an average of 23 minutes after posterior lumbar surgeries.[12] These findings were further supported by Vaidya et. al. in a retrospective study of 63 patients undergoing lumbar spinal fusions.[22] We hypothesize that the lack of significance difference in the present trial is secondary to lower patient numbers.

There is paucity of spinal literature comparing the incidence of perioperative adverse events between non-obese patients and their obese counterparts. In 2007, Patel et.al.were the first to demonstrate that increased BMI elevates the risk of significant postoperative complications after degenerative thoracolumbar spinal procedures. Two other groups have since confirmed these results in retrospective reviews. Rihn et al. correlated obesity with increased infection rates in a study of 389 patients undergoing surgery for degenerative spondylolisthesis.[12] Djurasovic etal. reported adverse event rates of 17.4% in non -bese and 28.4% in obese patients, reaching statistical significance.[21] These authors also reported statistical significance in wound related complications between the two groups.

In the first prospective clinical trial examining this issue, Yadla et. al. evaluated the relationship between obesity and incidence of perioperative complications in a general cohort of thoracolumbar degenerative spine surgery patients.[7] Restricting the analysis to 87 thoracolumbar cases, BMI did not correlate with increased risk of either major or minor complications ($p=0.12$, $p=0.19$, respectively). The authors concluded that BMI failed to correlate with increased risk of minor complications and "only weakly" correlated with increased risk of major complications, despite p value of 0.05.[7] Interestingly, the study was flawed by much heterogeneity among surgical procedures as only 24 of 87 patients actually underwent a posterior lumbar fusion procedure and the number of revision surgeries was not reported. This trial remains the only prospective publication on the topic to date.

There are several differences between Yadla et.al. report and the present study that we believe account for conflicting results. As previously stated, the current study design eliminated

numerous variables that potentially could affect the incidence of adverse events. We focused on isolating the impact of BMI on only posterior lumbar instrumented fusions for degenerative pathology in patients with no previous lumbar surgical procedures. This was done because it is the surgical approach, pathology, and anatomical location responsible for the overwhelming majority of all surgeries performed to alleviate low back pain in the United States. The Yadla et.al. report, however, encompasses much broader inclusion criteria and thereby introduces bias when we apply their results to our patient population. The authors concede that patients with fusion procedures were more likely to suffer complications, reaching statistical significance (p=.05). However, they did not offer a subgroup analysis to compare complication rates among obese and non-obese patients undergoing fusions in their cohort. Therefore, we believe our report, devoid of many variables, more accurately reflects the impact of body habitus on posterior lumbar fusion procedures.

Delineating factors responsible for perioperative adverse events possesses a direct correlation to overall healthcare costs. Whitmore et.al. prospectively evaluated patient comorbidities and perioperative complications after spinal surgery as well as their effect on the healthcare costs to society.[30] Cases with major complications totaled $13,714.88 more costly than those with minor complications ($p = 0.0001$). Specifically, wound complications alone were associated with statistically significant costs ($4,067, $p =0.0004$).

Shamji et al. conducted a large-scale study to evaluate the effects of body habitus on mortality, complications, and resource utilization for lumbar spine fusion. Data for 244,170 patients who underwent thoracolumbar or lumbar spine fusion for degenerative disease between 1988 and 2004 were reviewed from the Nationwide Inpatient Sample (NIS) database. Complications of accidental injury were more frequent in both the obese and morbidly obese groups ($p=0.01$).[23] Resource utilization also followed these trends, with substantially higher charges and greater likelihood of non-routine discharge to assisted living in the morbidly obese population.

Similarly, Kalanithi et al. conducted a retrospective cross-sectional study of all spinal fusions in California from 2003 to 2007.[20] In total, 84,607 admissions were identified, of which 1,455 were morbidly obese. Mortality among the morbidly obese was slightly higher (0.41 vs. 0.13, $p < 0.01$) as were average hospital costs ($108,604 vs . $84,861, $p < 0.0001$).[20] Length of stay was longer as well (4.8 d vs . 3.5 d, $p < 0.0001$). Restricting analysis to posterior lumbar fusions only, a statistically significant difference was established between normal weight and morbidly obese patients in both resource utilization and LOS ($20,092 more and 1.07 days longer mean stay, $p<0.0001$).[20]

Perhaps the inflated up-front health care costs associated with obesity could be acceptable in the setting of favorable long term clinical outcome for these patients. However, available literature fails to support this hypothesis. In fact, two large trials evaluating long-term clinical results in large patients suggest inferior results. To assess the association between BMI and clinical outcomes Knuttson et al. evaluated 2,633 patients undergoing surgery for lumbar stenosis (LS) who also completed 2-year follow-up in the Swedish Spine Register. A BMI$\geq$30

was associated with greater odds of dissatisfaction after surgery and inferior results at the 2-year follow-up. Although obese patients achieved significant pain reduction, better walking ability, and improved quality of life after surgical treatment of LS, obesity was, nonetheless, associated with a higher degree of dissatisfaction and poorer outcomes after surgery for LS.[24] In another study, Rihn etal. performed subgroup analysis of the SPORT database investigating surgery for lumbar stenosis and degenerative spondylolisthesis (DS) in obese patients with significant follow-up. Obese patients with DS had a higher postoperative infection rate (5% vs . 1%, $p = 0.05$) and twice the reoperation rate at 4-year follow-up (20% vs 11%, $p = 0.01$).

The healthcare costs and long term clinical analysis associated with obesity evaluated in the context of our results suggesting greater complication rates in obese patients should encourage spine surgeons to re-examine their patient selection criteria. We do not suggest that surgical interventions in obese patients be abandoned. However, we believe operations, especially in the morbidly obese, should be reserved for isolated cases where extensive conservative treatment course has been implemented and weight loss measures been undertaken. When proceeding with interventions, the surgeon should be prepared to encounter perioperative complexities, longer procedure times, and decreased clinical outcome. These issues need to be thoroughly addressed with the patients while obtaining surgical consent. Prior to this study, both senior surgeons hypothesized that surgical procedures aimed at alleviating back pain wound potentiate future weight loss. Contrary to this, Vaidya et. al. followed obese and morbidly obese patients after a lumbar fusion for an average of 20.4 months and found that no weight loss occured after spinal surgery.[22]

It may be prudent to consider alternative therapies for obese patients with low back pain. There is evidence to suggest weight loss alone may be effective in treating this symptoms.[25] Bariatric surgery is a well established procedure for significant weight loss. Recently, several authors investigated the possibility of bariatric surgery in obese patients with axial back pain and achieved promising results.[25] In 2009, Khoueir et.al. prospectively evaluated 58 consecutive patients with morbid obesity and chronic axial low back pain undergoing bariatric surgery with a 12 month follow-up. This study suggested that the substantial weight reduction after bariatric surgery may be associated with moderate reductions in preexisting back pain at 1 year.[25] Most recently, Lidar et.al. prospectively investigated the effect of significant weight reduction on intervertebral disc space height, axial back pain, radicular leg pain, and quality of life in 35 morbidly obese patients.[31] The mean BMI decreased from 42.8 to 29.7. The L4–L5 disc space height increased from 6 ± 1.3 mm, presurgery to 8 ± 1.5 mm 1 year postsurgery ($p < 0.001$) while both axial and radicular back pain decreased markedly after surgery ($p < 0.001$).

There are several limitations to the present investigation. We are continuing to prospectively enroll patients but thus far have a small patient cohort. Larger patient number is needed to improve the statistical power of our analysis. We also made no attempt to evaluate long term clinical outcomes in our patient cohort. Moreover, our trial was not designed to assess adverse events after hospital discharge.

Conclusion

In conclusion, increasing BMI carries a risk of greater perioperative complications and longer length of stay in obese patients compared to their non-obese counterparts. We believe this is the largest prospective cohort evaluating this issue for naïve lumbar fusion participants. Healthcare costs associated with obesity as reported in the literature should encourage spine surgeons to re-examine their patient selection criteria. Weight loss measures including bariatric surgery should be strongly encouraged as early indications point to symptomatic improvement among obese patients without spinal surgery.

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Comparison of O-Arm vs. Fluoronav Image Guided Lumbar Pedicle Screw Placement: A Single Institutions Experience

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Introduction

Pedicle screw fixation is a widely used technique to achieve rigid fixation of the thoracic, lumbar, and sacral spine. It is an effective technique utilized to augment fusion for the treatment of fractures, spondylolisthesis, scoliosis, tumors, and appropriately selected cases of degenerative disk disease with instability. Furthermore, the biomechanical strength of the construct is directly related to the accuracy of instrumentation placement. Although many surgeons have become adept with placement of pedicle screws, considerable knowledge and technical skill are required for accurate pedicle screw placement. The evaluation of accuracy for transpedicular instrumentation is a subject of great interest to the spine surgery community as we attempt to limit complications and improve patient outcomes. This has led to numerous published evaluations of the accuracy of pedicle screw placement and to the development of innovative techniques to improve the accuracy of instrumentation. In this article, we present our experience with O-Arm/Stealth (Medtronic Navigation, Louisville, Colorado) guided pedicle screw placement, analyzing pedicle screws placed over the last four months using the grading system of Sclafani et al.[5] We compared these results with those from a prior group of patients who received pedicle screw instrumentation placed with the image-guided assistance of FluoroNav/Stealth.

Methods

Patient Population

Between January 2012 and June 2012, and January 2013 and April 2013, 86 pedicle screws were inserted into 19 patients who underwent posterior spinal instrumentation for treatment of degenerative disk disease with instability, spondylolisthesis, fractures, or tumor using intraoperative O-Arm/Stealth based image-guided navigation. All instrumentation was placed under the supervision and direction of the senior neurosurgeon. A comparison group of 14 consecutive patients who had 82 pedicle screws inserted utilizing Fluoronav/Stealth guidance between January 2008 and June 2008 and who had postoperative CT scans performed within 48 hours of surgery, were also evaluated in this analysis.

Operative Technique

In the O-Arm group, patients underwent induction of general anesthesia and were placed prone on a Jackson table. Surgical exposure was carried out in routine fashion. If it was determined that revision of previously placed hardware was needed, the old hardware was removed prior to O-Arm or FluoroNav image acquisition. In all cases, a reference tracker was

secured to the spinous process of the vertebral level above the planned construct. The entire operative field was subsequently covered with sterile drapes, allowing only the reference tracker to be visualized. The surgical instruments were wheeled away from the surgical field on their sterile table. The O-Arm was opened, wheeled into position, and subsequently closed around the patient. Following O-Arm image acquisition, the drapes were removed, and the wound was re-exposed. Using this technique, no patient in our series suffered a wound infection. The 3-D volume dataset, obtained by the O-Arm, was uploaded into our stealth navigation integrated, spinal instrumentation suite at Cooper University Hospital. Image acquisition time was <1 minute in all cases. Coronal, axial, sagittal, and trajectory views were available to the surgeon in real-time during drilling and tapping of the pedicle tract. Prior to placement of screws, the pedicle tract was palpated using a ball-tipped "feeler" probe to assess each pedicle for cortical breech. After all pedicle screws were inserted, rods and set screws were placed on each side thus completing the screw-rod construct. A final intraoperative O-Arm scan, through the construct region, was obtained to confirm satisfactory placement, trajectory, and screw length prior to closure.

Patients in the FluoroNav/Stealth group underwent similar procedures for induction, exposure, and decompression for the same indications. Prior to instrumentation, a FluoroNav equipped C-Arm was wheeled into position and draped in sterile fashion. In all cases, a reference tracker was secured to the spinous process of the vertebral level above the planned construct. Following image acquisition, the C-Arm was removed. No patients suffered a wound infection using our image acquisition technique. The obtained 3-D dataset was uploaded into our stealth navigation integrated, spinal instrumentation suite at Cooper University Hospital. Following surgery, all patients underwent CT scanning within 48 hours to verify satisfactory placement of instrumentation.

Postoperative Evaluation

Using the scoring technique of Sclafani et al.[5], the accuracy of lumbar pedicle screws, which were placed utilizing O-Arm/Stealth image-guidance were compared to the accuracy of lumbar pedicle screws, which were placed utilizing FluoroNav/Stealth image-guidance. Using this same technique, we compared the accuracy of lumbar pedicle screws, which were placed on the patient's left side to the lumbar pedicle screws, which were inserted on patient's right side. This allowed us to validate the scoring system of Sclafani et al.[5], as the senior neurosurgeon placed all left sided pedicle screws while assisting the resident during right sided lumbar pedicle screw placement in both the O-Arm and FluoroNav groups.

Evaluation of Accuracy Using a Quantitative Screw Accuracy Scoring System

The technique of post-operative, radiographic pedicle screw assessment, originally described by Sclafani et al.[5], scores pedicle screw placement on six graded parameters: length, axial, and sagittal trajectory, and for medial, superior, inferior, and lateral cortical breeches. Ten possible points are given for each pedicle screw. A score of 10 was given for an ideal screw that

had the following characteristics: (1) screw length equivalent to three-fourths the length of the vertebral body, (2) screw trajectory within five degrees of the axis of the pedicle, (3) placement parallel to the superior endplate in the sagittal plane, (4) absence of inferior or superior cortical breaches, (5) absence of medial cortical breach, and (6) absence of lateral cortical breach. Each screw was scored with respect to these parameters.

Results

Of the 140 pedicle screws that were placed using intraoperative O-Arm/Stealth based guidance, we achieved a mean accuracy score of 9.05 $\pm$ 1.15. Although there was a strong trend toward more accurate pedicle screw placement utilizing the O-Arm/Stealth, this score was not statistically different from the mean accuracy score of 8.84 $\pm$ 0.97 we obtained in the 82 pedicle screws we inserted utilizing FluoroNav/Stealth guidance (P = 0.16).

To validate the scoring system of Sclafani et al.[5], we compared all pedicle screws which were placed on the patient's right side to those placed on the patient's left side. The attending neurosurgeon placed all of the left sided pedicle screws while assisting the resident in placing the right sided pedicle screws. Of the 110 total right sided pedicle screws, which were inserted utilizing either technology, we obtained a mean accuracy score of 8.82 $\pm$ 1.11. Subgroup analysis revealed mean accuracy scores of 8.51 $\pm$ 1.00 for the 41 right sided pedicle screws, that were placed using the FluoroNav, and 9.13 $\pm$ 1.1 for the 69 right sided pedicle screws that were placed using the O-Arm. There was statistical significance between these two groups (P = 0.004). When we analyzed the 112 left sided pedicle screws, which were placed using either technology, a mean accuracy score of 9.1 $\pm$ 0.86 was obtained. Subgroup analysis revealed mean accuracy scores of 9.17 $\pm$ 0.83 for the 41 left sided pedicle screws, which were placed using the FluoroNav, and 9.18 $\pm$ 0.78 for the 71 left sided pedicle screws, which were placed using the O-Arm. There was no statistically significant difference between these two groups (P = 0.94). The difference of the mean accuracy scores of the left sided pedicle screws, which were placed using either technology compared to the mean accuracy scores of the right sided pedicle screws, which were placed using either technology revealed a statistically significant difference (P = 0.008). Comparing the mean accuracy scores of the left and right pedicle screws, which were placed using FluoroNav, revealed a statistically significant difference (P = 0.002). This we hypothesize was secondary to the limited exposure the then second-year resident had in using this technology compared to the attending neurosurgeon. Comparing the mean accuracy scores of the left and right sided pedicle screws, which were inserted using the O-Arm, no statistically significant difference was found (P = 0.76). We believe this could have been secondary to the experience acquired by the resident during the final two years of his training who has become accustomed to placing lumbar pedicle screws, in addition to using this newer technology. Procedure time and radiation exposure where not analyzed as part of this study.

Discussion

Misplaced screws represent the most frequently reported pedicle screw complication with rates of misplacement ranging from 1.2% to 28.8% in various studies. Accurate pedicle screw placement requires that the surgeon conceptualize and understand each patient's 3-D spinal anatomy. Several image-guided pedicle screw insertion techniques have been developed to assist the surgeon in optimizing pedicle screw placement; reducing the frequency of malpositioned screw-related complications, optimizing patient outcomes as well as reducing radiation exposure to the patient as well and operating room staff. Currently, pedicle screws are placed by free-hand technique through the identification of reliable anatomic landmarks, and with or without the assistance of intraoperative fluoroscopy, or real-time, image-guided, navigation systems. Compared to intraoperative fluoroscopy, real-time image-guided navigation systems have helped surgeons achieve more accurate and safe placement of posterior spinal instrumentation[2,3,6,7,8].

Previous methods to assess pedicle screw accuracy have been inconsistent and relatively insensitive. In most series, thousands of pedicle screws are required to reach statistically significant conclusions. Previous studies have assessed the accuracy of pedicle screw placement in both open and minimally invasive surgery (MIS), through the application of various scoring systems to postoperative computed tomography images. These studies evaluate the accuracy by recording the presence or absence of a cortical breach or through grading in terms of breach severity. Assessment of so few parameters results in an insensitive method of evaluation. As a result, large sample sizes have been required to discern the accuracy between techniques. A recent study by Parker et al.[4], evaluated the accuracy of insertion of 6,816 pedicle screws by freehand technique. They used a scoring system that a single parameter was the absence or presence of a cortical breach. Another study, conducted by Devito el al.[1], attempted to increase the sensitivity of accuracy assessment through discrimination of breach severity based on increasing 2-mm increments of screw protrusion outside the pedicle. They used 3,271 pedicle screws in their evaluation. Sclafani et al.[5], developed a graded numeric scoring system that compares the 3-D position of a given pedicle screw relative to an ideal, "perfect" screw. We chose to use their system to assess our pedicle screw accuracy because it was a simple, consistent method, which did not require a large sample size to detect statistical significance.

In our series, O-Arm/Stealth guided insertion of lumbar pedicle screws did not result in accuracy scores, which were statistically different from those, which were inserted using FluoroNav/Stealth guidance. Subgroup analysis demonstrated that the pedicle screws placed by the attending neurosurgeon (left-sided pedicle screws) were statistically more accurate than those that were placed by the resident (right-sided pedicle screws). This was especially the case for screws that were inserted using FluoroNav/Stealth guidance. Statistical significance was lost when comparing O-Arm/Stealth guidance accuracy scores that were inserted by the attending neurosurgeon (left-sided pedicle screws), to those that were placed on the right side by the neurosurgical resident. The resident's accuracy was significantly improved with utilization of O-Arm/Stealth technology. Confounding this result however is the experience gained by this same

neurosurgical resident over which time, this facility transitioned from FluoroNav to O-Arm image acquisition.

Conclusion

Using the scoring system Sclafani et al.[5], our results demonstrate no significant difference in the accuracy scores of the pedicle screws we have placed using the FluoroNav and the O-Arm. Although statistical significance was not reached, there was a strong trend for more accurate lumbar pedicle screw placement by the resident using the O-Arm. We found a statistically significant difference in the mean accuracy scores of the attending physician compared to the resident physician in the placement of lumbar pedicle screws using FluoroNav/Stealth image-guidance. This we hypothesize was secondary to the surgical experience acquired by the attending neurosurgeon compared to the experience of the second year neurosurgery resident. This discrepancy was lost as we transitioned to using O-Arm/Stealth image-guidance. Although this newer technology is a useful tool, which can be used to improve pedicle screw insertion accuracy, it should not be used a crutch. This newer technology does not replace the knowledge one must acquire through training on how to place lumbar pedicle screws without the assistance of image-guidance, as there is significant opportunity for mechanical breakdown of these devices, as well as deterioration of image accuracy over the course of a procedure.

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Cervical Facet Fractures Associated with Focal Kyphotic Deformity: Predicting the Need for Surgical Intervention.

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Introduction

Cervical facet fractures are an uncommon injury, however at high volume trauma centers, they can be seen with some frequency. It is estimated that the cervical spine is injured in approximately 2.4% of blunt trauma victims[7,18] with unilateral cervical facets accounting for 2-3% of acute traumatic cervical spine fractures[8,14]. The mechanism of a cervical facet fracture is thought to be caused by extension and compression, with a rotational component in unilateral injuries[5]. Management of isolated cervical facet fractures is not definitive, and the literature supporting treatment strategies is sparse, but treatment consideration of cervical facet fractures must be consistent with the management of any cervical spine injury: relieve compression of neural elements, restore normal alignment, establish stability, provide freedom from post-injury pain or delayed neurological injury, and attempt to return the patients to their pre-injury status[4]. Management of unilateral cervical facet fractures can often be managed conservatively with rigid cervical orthoses or halo vests[9,15,17]. There have been some attempts to identify subtypes that are more prone towards instability and thus may dictate surgical intervention[16]. In addition, with the evolving high-definition of current computed tomography and magnetic resonance imaging, evaluation of fracture patterns may help to further delineate appropriate treatment algorhythms[9,17].

At our institution, predicting the need for surgical intervention in a patient with a cervical facet fracture is multifactorial. Mechanism, radiographic and morphological characteristics, involvement of ligamentous structures, neurological status and the degree of pain are all considerations that are taken into account. There is a modest array of literature supporting the surgical treatment of cervical fracture-dislocations and isolated jumped/perched facets due to the high propensity of failing non-operative management[2,3,20]. This is supported by the concept that these types of injuries often involve the disruption of the joint and its supporting ligamentous structures, which tend to heal more unpredictably than pure boney fractures. Identification of ligamentous disruption in cervical spine injuries is an important component in predicting which fractures will heal with non-surgical management[19]. However, in the absence of significant facet disruption, there is a paucity of literature supporting the use of surgical intervention for facet/lateral mass fractures without dislocation. At Virginia Tech Carilion Clinic, we designed a pilot study with the purpose of assessing traumatic cervical fractures and identifying which patients are failing treatment, specifically non-surgical management. After noticing a significant incidence of cervical kyphosis in patients with facet fractures requiring delayed surgery, we attempted to further define the role of kyphosis in the setting of traumatic cervical facet fractures

and the ultimate need for surgical stabilization. This is the first study to our knowledge that correlates the need for surgery in patients with cervical facet fractures with focal kyphosis.

Methods

A retrospective review was conducted, consisting of 378 cervical spine fractures admitted to our institution during a 32-month period (August 1, 2008 to April 30, 2011). The initial patient database was accumulated by querying our electronic medical record (EPIC) by using ICD-9 codes consistent with traumatic cervical fractures with values ranging from 805.00 to 805.08, 805.2, and 806.00 to 806.09. We further refined our report by individual patient chart review to include only patients with superior and inferior facet fractures, single or multiple levels, unilateral and bilateral facet fractures of the sub-axial cervical spine (C3-C7). Patients with facet fractures of C1, C2, T1 or below were excluded unless they had a facet fracture that involved the C3-C7 vertebral levels. Accumulated data included ICD-9 codes, admission/treatment dates vs. surgical dates, radiological identification and description of cervical fractures and facet/lateral mass fractures, types of cervical orthoses, the amount of listhesis, neurological injury, SLIC scores and documented reason for delayed surgery (if patient received delayed surgical intervention). We independently reviewed the fracture type and the amount of focal or global kyphosis, if any. Angles were used measuring an intersecting angle between the inferior endplate of the vertebral body of the level above the facet fracture and the superior endplate of the vertebral body below. In the case of a combined compression fracture, the angle was chosen perpendicular the level of the anterior aspect of the vertebral body. In the event of a globalized kyphosis, thought to be unrelated to fractured level, this was notated.

We asked two questions to be evaluated statistically. First, is there an association between the need for surgery and cervical facet fractures with focal kyphosis. Second, is there an association between the need for delayed surgery and cervical facet fractures with focal kyphosis. A Chi-Square test was run on each contingency.

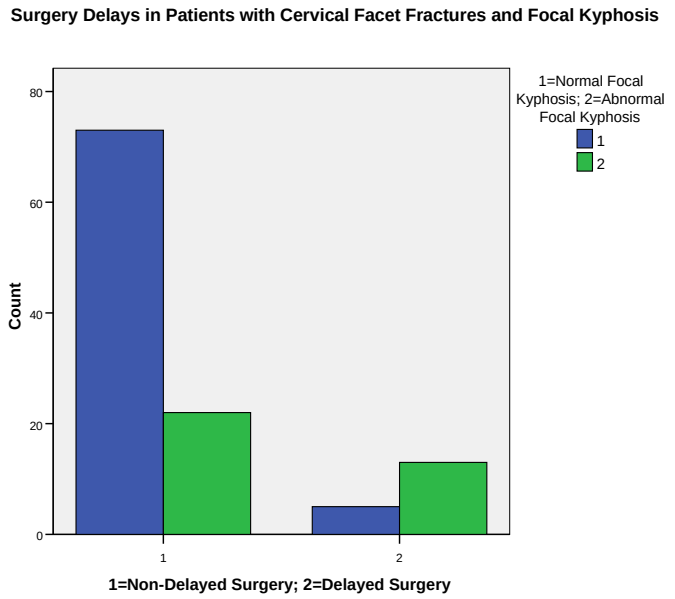
Results

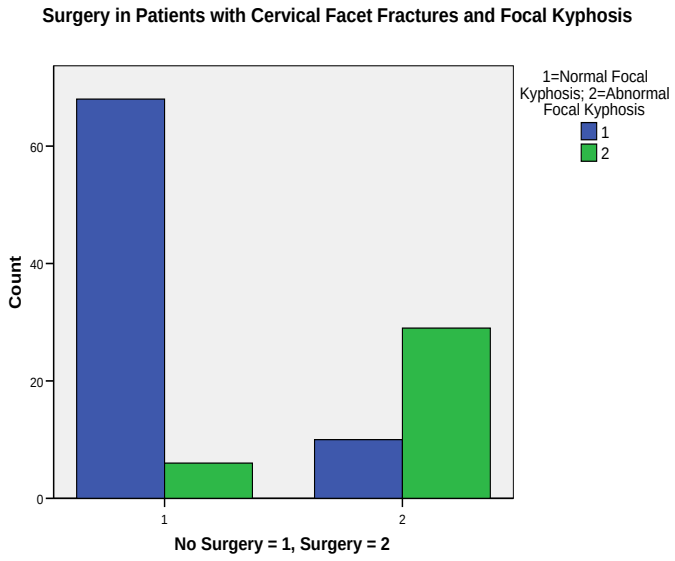
We identified 378 cervical fractures, 114 patients sustaining fractures of 1 or more facets. In total (patients receiving both immediate and delayed surgery), 39 patients received surgical intervention for cervical fractures of which a facet fracture was a component. 11 patients received anterior alone surgery, 22 patients received posterior alone surgery and 5 patients received anterior/posterior surgery; there was one patient that was offered surgical fixation, but never showed for surgery. Of patients requiring surgical intervention, kyphotic deformities ranged from non-kyphotic angles (0 degrees) to 23 degrees with an average of 6.15 degrees of kyphotic angulation. Overall cervical kyphosis ranged from 61 degrees lordotic angle to 30 degrees kyphotic angulation. All patients were placed in collars. Average SLIC scores for patients requiring surgical intervention were 4.82. Listhesis ranged from 0 to 13mm with an average of 3.40 mm of listhesis. There were 3 incomplete spinal cord injuries (SCI), 9 complete

SCI. 7 patients either presented with or developed radiculopathies in the form of root weakness, 5 had radiculopathies in the form of pain/parasthesias. 15 patients were intact.

With respect to patients receiving delayed surgery, there were 18 patients that received delayed surgery. 11 of these patients developed progressive listhesis, 4 patients developed progressive radicular pains, 7 patients developed significant kyphotic deformities, and one patient with ankylosing spondylitis developed a delayed EDH with progressive root weakness in this group. 4 patients received anterior alone procedures, 2 patients received combined anterior/posterior fixation and 12 received posterior only surgery. There was 1 patient that presented with focal kyphosis of 3 degrees at initial presentation, with chronic pain after conservative management and offered surgery twice, but didn't show up for scheduled surgery. Of these patients, focal cervical kyphosis originating at the level of the facet fracture ranged from 0 to 19 degrees. There were only 4 patients without any evidence of kyphosis. The average kyphotic deformity was 6.03 degrees with an average cervical lordosis of 9.84 degrees. 4 patients presented with significant generalized cervical kyphosis of > 10 degrees (non-focal), 2 patients did have evidence of loss of lordosis. The average listhesis was 1.34 mm, ranging from 0 to 4mm. 10 of 18 patients were neurologically intact, 2 patients presented with root weakness, 1 patient with a central cord syndrome, 4 patients with radicular pain, and 2 patients with delayed root weakness.

A Chi-Square Test found p-values of 0.000 when testing for statistically significant associations between cervical facet fractures with focal kyphosis and the need for surgical intervention, as well as when testing for the need for delayed surgery in our patient population with cervical facet fractures and associated focal kyphosis. There were no statistically significant associations ($p \leq 0.05$) when testing for other contingencies, including the amount of listhesis, the presence of neurological deficits, the type or degree of lateral mass fracture or the type of cervical orthosis in the patient population that received delayed surgery.





Discussion

The management of acute cervical fractures are impacted by a multitude of factors. Physician experience and preference often plays a role in deciding between surgical and non-surgical intervention as well as the types of intervention. Studies have shown that expert opinions are often relatively homogeneous across injury types[12]. However, there has been little published on identification of injuries that are isolated to facet joints, and the need for surgical stabilization. Dvorak et al.[6] suggest that patients with unilateral facet injuries of the sub-axial cervical spine

reported levels of pain and disability that are significantly worse than those of the healthy population and that those treated non-operatively reported worse outcomes than those treated operatively. This study is poorly generalizable to our study however, in that their patient population included patients sustaining injuries ranging from simple facet fractures, to patients with significant facet-dislocations. Lee et al.[11] described a subgroup of patients with unilateral lateral mass fractures with rotational instability due to horizontal lateral mass fractures - their nonsurgical favorable outcome rate was only 8% (3 of 39 patients), similar to the non-operative treatment results that Rorabeck et al. has reported[15]. In addition, data from the University of New Mexico Hospital found a significant amount of patients with cervical facet fractures that subsequently developed significant subluxation (3mm or more) after treatment with a cervical orthosis, requiring cervical fixation for treatment failure[9].

The role of ligamentous injury cannot be understated[19]. Magnetic Resonance Imaging (MR) has become increasingly available and routinely used in the evaluation of trauma[1,9]. However, its role in the acute setting will likely never surpass the utility and diagnostic value of computed tomography. In addition, the increasing scrutiny over health care spending may further limit the wide spread use of MR in this patient population. In our series, we found that there is a significant chance for treatment failure, when attempting to treat patients with facet fractures and accompanying focal kyphosis with non-surgical management. Though CT is well regarded as the gold standard in trauma imaging for the spine, we feel that in patients with cervical facet fractures, the presence of focal kyphosis likely implies ligamentous incompetence, which may impart a more significant injury[19] and subsequent need for more aggressive management. In fact, a post-hoc analysis of our data showed that of 18 patients requiring delayed surgery, only 12 patients received MR imaging – however, 10 of 12 patients (83%) showed imaging consistent with ligamentous injuries.

Conclusion

Our study attempts to identify a subgroup of patients with cervical injuries that are at risk of failing non-surgical treatment. Our data indicates that in patients with focal kyphosis associated with traumatic cervical facet fractures, 61% developed progressive listhesis, 39% had persistent or progressive pain and 39% developed progressive kyphosis. In the absence of traumatic disc herniation or disc space disruption, significant dislocation/listhesis, accompanying vertebral body fracture/retropulsion, or neurological injury, the presence of focal kyphosis may be a radiographic finding implicating the need for more scrutiny with respect to surveillance and a more heightened consideration for initial surgical management.

We acknowledge the limitations of this study including its retrospective nature and accompanying non-blinded bias as well as the small population size. However, we feel that by identification of patients at risk for treatment failure, this study may provide a stepping-stone for further investigation into advancement of more efficacious and successful treatment protocols.

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Clinical Evaluation of the AESCULAP Miethke PAEDI-GAV Valve for Hydrocephalus in Children

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Abstract:

Objective: A single center, randomized, non-blinded prospective study was performed to evaluate the efficacy of the Aesculap Miethke PAEDI-GAV valve performance in comparison to standard valves currently used in our facility in the pediatric population for shunt dependent hydrocephalus.

Methods: Patients under the age of 18 that had a clinical diagnosis of hydrocephalus and who were candidates for a ventriculoperitoneal shunt system These patients could be shunt naïve patients or patients with previous history of shunts and shunt malfunction. They were then randomly selected to receive either a protocol valve or a control valve. Once either the protocol valve or control valves were implanted into the system, time to explantation due to valve failure was reported as a final end point. These patients also received imaging studies at 12 and 24 months and at the time of valve failure. Evan's ratios data were collected from these images and were compared with the pre-shunt images and change Evans ratios were used as an objective means to evaluate shunt function between the two groups.

Results: There were 26 valves that failed in the trial. Of these valves 15 (58%) were trial valves, and 11 (42%) were control valves. The average time to failure in the control group was 274 days, and time to failure in the test group was 413 days. Statistical analysis using the chi-square log rank method showed no statistical significance (P=.386) between the two groups or Evans ratios at 12, 24 months and time of failure (P= 0.74, 0.449, 0.056 respectively).

Conclusion: There was no statistical difference in time to failure between the control valve group and the Miethke PAEDI-GAV valve trial group. Also, there was no statistical difference in using Evans ratio as an objective means to evaluate valve function between the two groups.

Keywords: Hydrocephalus, Miethke PAEDI-GAV valve, Evans Ratio

Introduction

Treatment of infantile hydrocephalus results in the placement of at least 125,000 cerebral spinal fluid (CSF) drainage systems annually in the United States. [1] The estimated annual cost of these procedures is 100 million, with shunt malfunction and revision responsible for a large proportion of the expense. Historically, about 80% of shunts fail within 12 years of implantation, and more recently the UK Shunt Registry has reported a failure rate of 35% over five years in the United Kingdom. [2] The most common time for shunt malfunction is in the first six months, commonly due to infection or mechanical failure.

One of the major causes of shunt valve malfunction is inadequate drainage or over-drainage due to changes in intracranial pressure (ICP) as the patient assumes different postures. Shunt valves that allow proper CSF flow when the patient is prone or supine may not function effectively when the patient stands or sits. Over drainage, or "siphoning" may occur in the erect position, causing the cerebral ventricles to become slit-like and producing additional neurologic complications.

The Aesculap Miethke PAEDI-GAV valve has been developed to alleviate these problems by using gravitational force to maintain ICP levels that are nearly identical to physiologic pressures regardless of the patient's body position. This new valve is unique in that it combines a standard ball-in-cone mechanism to regulate ICP what the patient (and valve) is horizontal, and a gravitational valve mechanism to increase ICP to prevent siphoning what the patient is upright. The gravitational valve also uses movable balls. These balls do not contribute any resistance with the patient is horizontal, but their weight does increase resistance and therefore slows CSF flow with the patient is vertical. Furthermore, the Miethke PAEDI-GAV valve has a robust titanium casing that helps to reduce the effects of external factors, such as atmospheric pressure and the weight of the surrounding tissue on shunt function. Finally, this valve has been specifically designed for use in infants and small children.

The Miethke PAEDI-GAV valve was designed by Christoph Miethke (Christoph MiethkE GmbH & Co. GK) and introduced into clinical practice in the early 1990s. It has become popular in Germany [3 -- 5] were shown to perform effectively in bench-top studies by the United Kingdom Shunt Evaluation Laboratory at Addenbrooke's Hospital, Cambridge, UK in 2003. [2] The FDA has granted the Aesculap Miethke PAEDI-GAV valve 510(k) clearance.

Currently six types of Miethke PAEDI-GAV valves are available with different opening pressures. The valve with the lowest opening pressure is set to open at 40 mm H_2O (2.9 mm Hg) in the horizontal position and 140mm H_2O (10.3 mmHg) in the vertical position. The valve with the highest opening pressure is set to open at 90 mm H_2O (6.6 mmHg) in the horizontal position in 290 mm H_2O (21.3 mmHg) in the vertical position. Each level is coded on the valve to allow the shunts to be identified on X-ray following placement.

Objectives

The overall purpose of this clinical evaluation was to assess the performance of the Aesculap Miethke PAEDI-GAV compared to other commercially available valves in a prospective, randomized, non-blinded clinical trial for the treatment of hydrocephalus. The main criterion for performance was time to valve failure in days.

A secondary objective of this study was to measure change Evans ratios from implantation to endpoint as an objective means to evaluate valve function between the two groups after valve implantation.

Study Population

Ninety patients were enrolled at Children's Hospital of Michigan with age range from birth to 18 years of age who were candidates for ventriculoperitoneal shunting for hydrocephalus, and who met the selection criteria given in the protocol below. This included patients requiring initial shunt and shunt revision.

Study Design

The study design was a prospective, randomized, non-blinded clinical trial of pediatric patients less than 18 years of age. Patients selected for the study were randomized to either the Aesculap Miethke PAEDI-GAV valve group or to the control group. Patients in the control group received commercially available pressure control valves, chosen by the attending neurosurgeon at the time of surgery. Based on the current trends of our clinical practice, most of the control valves consisted of the Codman Hakim programmable valve, or the PS medical valve with or without a gravity-compensating accessory. Patients were followed for up to two years after shunt implantation, or at the time of any suspected shunt malfunction. Imaging studies of the brain, either CT scan or MRI, were obtained at 12 months and 24 months or at the time of valve failure. The key clinical endpoint of the study was the time to valve failure, and change in Evans ratio.

The study contained two arms, depending on initial versus revision shunting.

1. New patients requiring a first-time ventriculoperitoneal (VP) shunt. If randomly enrolled into Aesculap Miethke PAEDI-GAV group, they will receive the type 4/24(low pressure) valve if they are less than six months old, the type 9/24 (medium pressure) valve if they are six months to five years old, in the type 9/29(medium pressure) valve if they are 5 to 18 years old, according to the manufacturer's specifications. Teenage and adult patients will receive the Aesculap Miethke standard 10/40 or 10/50 valves if their height is 5'3" to 6'or >6', respectively.

2. Revisions of VP shunts in shunt dependent patients. If randomly enrolled in the Aesculap Miethke PAEDI-GAV group, they will receive the type 4/19(low pressure) valve or the type 4/24(medium pressure) valve if they are less than six months old, the type 9/24 valve if they are six months to five years old, and type 9/29 valve if they are 5 to 18 years old, according to the manufacturer's specifications.

The study was non-blinded since it was not possible to blind investigators to the identification of the valve once it has been implanted surgically.

During the study, follow-up evaluations assessed the clinical status of the patient and the functional status of the entire shunt system. Any revisions, including explants, complications, or other problems were documented.

Initial scanning, either with a CT or MRI, was performed at the time the study valve was implanted. This was done for both the protocol and control valve subgroups. Subsequently, follow-up imaging at 12 months and 24 months was obtained to evaluate for over versus under drainage of the shunt system. Also, any patient presenting with clinical symptoms of shunt malfunction had imaging obtained. If a valve had to be explanted for any reason, the pre-valve removal operative images were used for data collection. Evans ratio measurements were taken as described below.

Evan's ratio: The frontal horns of the lateral ventricles were measured at their greatest diameter at the level of the foramen of Monrow. At the same level, the diameter of the inner table of the skull was measured and the quotient between the frontal horns the inner table of the skull gave us the Evans ratio.

Exclusion criteria for the study included: Current anticoagulant therapy, known bleeding diathesis, or any active infection within three months of presentation for hydrocephalus, valve failure because of infection within the past three months, hygroma or cyst formation, any indication which would contraindicate V.P. shunting, expected life span of less than 24 months, inability to return for required follow-up evaluations, and inability to give informed consent.

Shunt malfunction was defined as any patient presenting with clinical Signs and symptoms of malfunction. Also, some patients had ancillary testing that corroborated shunt malfunction such as increased ventricular size on radiographic imaging, no or little CSF flow from needle tap of the shunt reservoir, slow or no clearing of radiographic contrast on shunt injection, ICP monitoring showing consistently high pressures, or fracture of shunt tubing. If at any time the patient was believed to have a shunt malfunction, operative exploration of the shunt was performed and the valve was left implanted if it was found to be functional.

Shunt infection was defined as any patient presenting with signs and symptoms of infection in which gram staining and cultures were positive for microorganisms, or if any of the shunt material eroded through the skin, or if there was a persistent CSF leak. If a shunt infection was diagnosed the entire shunt system was removed operatively and the patient was placed on external ventricular drainage for CSF rerouting until CSF cultures were clear.

Data

A total of 90 patients were initially enrolled in the study. Ten of these patients were excluded, 7 secondary to age criteria, 1 patient died of severe respiratory failure and did not meet the required 24 month life expectancy, one patient's implanted valve type was not recorded properly, and 1 patient received a control valve for a syringo-pleural shunt. Of the remaining 80 patients who were enrolled in the study, 19 were lost to follow-up (discussed later). The final total of patients was 61. 33 (55%) of these patients were male, and 28 (45%) of these patients were female. The youngest patient enrolled in the study was two days old and the oldest patient enrolled in the study was 17. The average age of the patients enrolled was 6.4 years of age.

The diagnoses requiring V.P. shunting were as follows: 14 (23%) had meningomyelocele, 12 (20%) had intraventricular hemorrhage, 8 (13%) had congenital hydrocephalus, 6 (10%) had aqueductal

stenosis, 6 (10%) had a tumor causing hydrocephalus, 3 (5%) had post-infectious hydrocephalus, 3 (5%) had an Arnold Chiari malformation, 1 (2%) had an arachnoid cyst, 1 (2%) had a traumatic brain injury, 1 (2%) was unknown, 1 (2%) had a Dandy Walker malformation, 1 (2%) had an encephalocele, 1 (2%) had hydrocephalus status post aneurysm rupture, 1 (2%) had unspecified obstructive hydrocephalus, 1 (2%) had Schizenephaly, and 1 (2%) had unspecified communicating hydrocephalus. (Figure 1)

aquedctual stenosis	10%	6
Arachnoid Cyst	2%	1
Chiari	5%	3
Dandy-Walker	2%	1
Encephalocele	2%	1
Hydro SP aneurysm rupture IPH	2%	1
IVH	20%	12
meningomyelocele	21%	13
meningomyelocele/syringopleu	2%	1
obstructive Hydro	2%	1
postinfectious hydro	5%	3
schizencephaly	2%	1
tumor	10%	6
unknown	2%	1
congenital hydro	13%	8
TBI	2%	1

Table 1: Indication for Shunting

A total of 61 valves were used in the trial. Of the control valves used, 20 (33%) patients received the Codman Hakim programmable valve, 1 (2%) received a PS-Medical low-pressure valve, and 9 (15%) received a PS-Medical medium pressure valve for a total of 30 (49%) control valves. A total of 31 (51%) study valves were used. Of these study valves, pressure settings were as follows; 1 (2%) were 10/40, 2 (3%) were 10/50, 0 (0%) were 4/24, 8 (13%) were 9/19, 11 (18%) were 9/24, and 9 (15%) were 9/29 (Figure 2).

Codman Hakim Programmable	33%	20
Miethke Paedi-Gav 10/40	2%	1
Miethke Paedi-Gav 10/50	3%	2
Miethke Paedi-Gav 4/24	0%	0
Miethke Paedi-Gav 9/19	13%	8
Miethke Paedi-Gav 9/24	18%	11
Miethke Paedi-Gav 9/29	15%	9
PS-Medical Low Pressure	2%	1
PS-Medical Medium Pressure	15%	9
# OF VALVES: 1	100%	61

Table 2: Valve Types

The patients that were excluded had the following data profile: 12 (63%) were male and 7 (37%) were female, 6 (32%) received control valves and 13 (68%) received trial valves, 6 (32%) had intraventricular hemorrhage, 3 (16%) had meningomyelocele, 3 (16%) had congenital hydrocephalus, 2 (11%) had an arachnoid cyst, 2 (11%) had traumatic brain injury, 1 (5%) had postinfectious hydrocephalus, 1 (5%) had a tumor, and 1 (5%) had an unknown cause for hydrocephalus. The average

age of these patients was 9.3 years of age. The youngest patient was three weeks old and the oldest patient was 17 years old.

Of all valves that were used in the study, 35 (57%) were still functioning at the end of the trial and 26 (43%) failed. Reasons for failure include: 6 (23%) with unspecified valve failure, 6 (23%) failed secondary to debris, 4 (15%) for infection, 2 (8%) four over-drainage, 3 (12%) for under-drainage, 1 (4%) ventricular catheter extrusion, 1 (4%) was converted to lumbar peritoneal shunt secondary to inability to maintain functioning ventricular catheter, 1 (4%) was externalized due to unspecified nonfunctioning system, 1 (4%) had fracture of the distal catheter, and 1 (4%) secondary to occlusion with tumor (Figure 3).

Still functioning	35	57%
Catheter extruded	1	4%
Converted to Lpshunt, prox revis	1	4%
Debris	6	23%
Externalized/nonfuntion system	1	4%
Fracture of distal catheter	1	4%
Infection	4	15%
Occluded w/tumor	1	4%
Overdrainage	2	8%
Underdrainage	3	12%
Valve fail	6	23%
Total Fail	26	43%
Total Valves	61	

Table 3: Reason for Failure

At the end of the study 35 (57%) of the valves implanted were still functional. Of these still functional valves, 19 (54%) were control valves, and 16 (46%) were trial valves. In the control valve group 13 (68%) were Codman programmable valves, 1 (6%) was a PS medical low-pressure valve, and 5 (26%) were PS medical medium pressure valves. In the trial valve group 7 (44%) were Miethke 9/29 valves, four (25%) were Miethke 9/24, four (25%) were Miethke 9/19, one (6%) was Miethke 10/50.

During the study 26 valves (43%) failed. Of these valves 11 (42%) were trial valves, and 15 (58%) were control valves. In control valve group 7 (64%) were Codman programmable valves, and four (36%) were PS medical medium pressure valves. In the trial valve group 7 (47%) were Miethke 9/24, four (27%) were Miethke 9/19, 2 (14%) were Miethke 9/29, 1 (6%) was Miethke 10/40, and 1 (6%) was Miethke 10/50.

During the study 46 (75%) patients had baseline imaging studies that could be used for Evans ratio and cortical mantle thickness measurements. The remaining 15 (25%) of patients whose baseline images could not be used were either due to severe brain anatomical defects making measurements impossible or unreliable (i.e. hemispherectomy) or the imaging studies were obtained at an outside facility and were on obtainable for research purposes. 11 (18%) patients had imaging studies at the time of failure. 20 (33%) of patients had 12 month follow-up imaging studies, and 23 (38%) had imaging studies at 24 months.

Statistical Analysis:

Data were initially summarized using descriptive statistics to describe the two study groups. Mean and standard deviation (SD) was be used for normally distributed continuous variables, Median and range for skewed continuous variable, frequency and percentage for the categorical variables. The data then were analyzed using the Kaplan-Meier surviving curve and Log-rank test to test the equality of survival functions between the two groups.

Also, to compare the two groups, t-test is used for normally distributed continuous variables and Mann-Whitney test for skewed variables. All tests are two-tailed test and a p-value of < .05 indicates statistically significant result.

Results

There were 61 valves used in the study; 30 valves were control and 31 were trail. 11 (37%) of control valves failed with average survival time of 274 days, while 15 (48%) of trail valves failed with average survival time of 413 days (table 4). We used Kaplan-Meier survival curve and the log rank test to test whether the two groups have the same survival distribution and found no statistical significant difference (P=.386) between the two groups. (Figure 1)

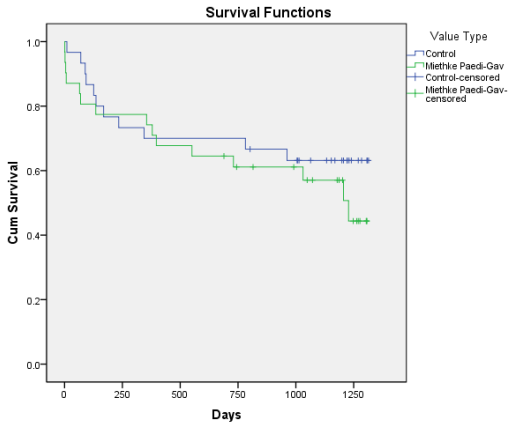

FIGURE 1

Group	N	Failed	Average Survival Time (Day)
Control	30	11(37%)	274
Trail	31	15(48%)	413
Total	61	26(43%)	354

Table 4

Evans ratio: The change in Evans ratio was calculated at 12, 24 months or at the time of valve failure. Out of those valves that failed, the control group showed a median increase in Evans ratio by 0.35 (Range of 0.16), and the trial group showed a median increase in Evans ratio by 0.31 (Range 0.234). Mann-Whitney test was used to test the difference. There was no statistical significance between the two groups in the change in Evans ratio at time of failure (P= 0.056). (Table 2)

For the valves that had images at the 12-month follow-up the control group showed a mean decrease in Evans ratio by 0.318 (SD 0.04), and the trial group showed a mean decrease in Evans ratio of 0.331 (SD 0.11). Student T-Test was applied to the data. There was no statistical difference between the two groups in the change in Evans ratios at the 12-month follow-up (P= 0.74). (Table 5)

For those valves that survived to 24-month follow-up imaging the control group showed a median decrease in Evans ratio by 0.315 (Range 0.645), and the trial group showed a median decrease in Evans ratio by 0.338 (Range 1.11). Mann-Whitney test was again used for this group. There was no statistical difference between the two groups in the change in Evans ratio at the 24-month follow-up (P= 0.449). (Table 2)

Group	Control			Trial		
Variable	12 month	24 month	End	12 month	24 month	End
N	12	12	4	8	11	11
Average	.318	------	----	.331	----	----
SD	.04	-----	----	.11	----	----
Median	-----	.315	.35	-----	.338	.31
Range	-----	.645	.16	------	1.11	.234
P- value	0.74	0.449	0.056	0.74	0.449	0.056

Table 5

Comments

One of the major problems with this study is the lack of data that could be included in the final analysis. Of the original 90 patients enrolled in the study, only 26 of them had data that was suitable for analysis of the end of the study. Although time to failure was proven to be not statistically significant, there was 139 day difference in the average time to failure between the control and the trial groups, with the trial valves tending to last longer periods of time. However, since we have only 26 data points we were not able to prove a statistical difference between the two groups. If we had more data points for our analysis we may have seen more of a statistical significance.

Similarly, in the Evans ratio sub analysis we had very few data points to use for our statistical analysis. Only 11 patients had imaging studies at time of valve failure, 20 at 12 month, and 23 at 24-month follow-up. Lack of imaging was multifactorial. Some patients were lost to follow-up and their

data could not be used. Other patients received imaging studies at outside facilities that could not be obtained. Others had imaging done postoperatively, however, images were not done at the 12 and 24 month intervals, therefore could not be used in analysis. Others could not be used due to severe defects that make measurements impossible.

All patients, except for a few who had severe defects, had their Evans ratios measured and recorded. This proved to be difficult in some patients, especially in patients with slit-like ventricles. In these patients, if the imaging cross-section was not done at the exact location of the foramen of Monro, the frontal horn of the lateral ventricle became very difficult to distinguish from the brain parenchyma. This added some error to the measurements as the width of the frontal horns had to be estimated at times.

The ability of the skull to change in a pediatric patient may make the Evans ratio more difficult to interpret. In the adult population, the calvarium remains relatively fixed, which makes determining an increasing ratio from hydrocephalus easier to interpret. Also, patients with slit-ventricle syndrome may not have extreme changes on neuroimaging, even though clinically they are suffering from obstructive hydrocephalus and or shunt malfunction. Putting all these points together, the Evans ratio may not be the measurement of choice for following pediatric shunted hydrocephalus and clinical correlation with neuroimaging is necessary.

Conclusion

We did not find any statistical difference in valve survival time between our control group and the Miethke PAEDI-GAV valve group. Therefore we conclude that the Miethke paediGAV valve is comparable to other standard valves we use in our practice. However, our numbers for analysis were low (n=26) at the end of the study. Higher numbers may have given the study more power to determine if there was a statistical difference.

Also, we did not find any statistical significance in using Evans ratio as an objective measurement tool for evaluating valve function between the control and trial groups at 12, 24 months or time of failure. Again, there was insufficient data at the end of the trial to power the study. We recommend using Evan's ratio as an adjunct to the patient's clinical presentation to evaluate shunt failure.

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The value of immediate postoperative MR imaging following endoscopic endonasal pituitary surgery

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Abstract:

Background: Although the value of early MR imaging has been justified for microscopic transphenoidal surgery, there is no literature evaluating immediate postoperative MR imaging following endoscopic endonasal resection of pituitary adenomas. We hypothesized that MRI of the pituitary gland performed on the first postoperative day is just as effective at detecting residual disease and/or reconstruction materials as the MRI at 3 months following surgery.
Methods: We retrospectively evaluated 102 consecutive patients who underwent endoscopic endonasal surgery for presumed pituitary adenomas. Sixty-four patients met the inclusion criteria with immediate and 3 months MR imaging. Imaging was evaluated by two sets of observers. The following parameters were assessed: enhancement pattern of the pituitary gland, pituitary stalk, nodular enhancement (residual tumor) or linear enhancement (non-tumoral) and residual reconstruction/packing materials.
Results: Gross total resection of the tumors with no cavernous sinus involvement was achieved in 49 out of 52 (94%) patients. Eleven out of 12 remaining patients with cavernous sinus invasion had residual cavernous sinus component visible on both immediate and 3 month MR imaging. The pituitary gland, position of stalk, and nasoseptal flap could be identified on both post-operative MRIs in all patients. The sensitivity and specificity for residual tumor detection on immediate MRI was 100% and 97.9%, respectively. The kappa index evaluating interobserver agreement for identification of residual tumor and packing/reconstruction material on immediate MR was 0.83 and 0.72 indicating near perfect and substantial agreement, respectively.
Conclusion: Immediate MR imaging performed following endoscopic endonasal resection of pituitary lesions provides accurate and reliable information regarding the presence of residual tumor compared to reconstruction and packing materials.

Key Words: endoscopic endonasal, pituitary adenoma, post-operative magnetic resonance imaging, transphenoidal
Running head: Immediate post-operative MR imaging

INTRODUCTION

Since the 1980s, magnetic resonance imaging (MRI) has become the accepted imaging modality for the radiographic assessment of the pituitary gland and sella [8, 12, 13, 17]. Preoperatively, pituitary gland adenomas and other sellar lesions can readily be distinguished from normal surrounding structures [16, 17, 23]. However, it is the general belief that it is often difficult to evaluate post-operative MR imaging for residual tumor following endoscopic transsphenoidal resection of these lesions due to swelling, presence of blood products, and materials used for reconstruction of the sellar floor [6, 10, 20, 21]. Although follow up MR imaging following endoscopic transsphenoidal surgery is common, it is not typically obtained in the early post-operative period [8, 12, 22, 24]. While there is no consensus as to the optimal timing for the first postoperative MRI, most surgeons wait several months allowing for regression of swelling, blood, and packing materials [6, 10, 20].

Currently, there are no studies evaluating the use of early postoperative MRI in endoscopic endonasal pituitary surgery despite its increased utilization. The objective of this study is to test the hypothesis that MRI of the sella/pituitary gland performed on the first postoperative day (POD#1) is just as effective at detecting residual disease as the MRI performed at 3 months following endoscopic endonasal resection of pituitary adenomas.

MATERIAL AND METHODS

After approval by the Institutional Review Board, a prospectively maintained database of 102 consecutive patients at Geisinger Medical Center (GMC) who underwent endoscopic endonasal transsphenoidal resection of sellar/suprasellar masses, presumed to be pituitary adenomas by MR imaging, was retrospectively reviewed between February 2009 and October 2011. Departmental protocol is for patients to have MR imaging on POD#1 and at 3 months following EES, unless a contraindication to MRI exists or the patient was lost to follow up. Patients who underwent expanded endoscopic procedures or patients with no POD#1 and /or 3 month MR imaging available for review were excluded from this series. Therefore, sixty four patients met the inclusion criteria with POD#1 and 3 month MR imaging following surgery in were included in the study. All patients had preoperative neuroendocrine evaluation and dedicated sellar MRI according to our institutional protocol. All patients underwent a formal neuro-opthalmological exam before surgery, unless no functional visual deficit was elicited on examination and the tumor was not touching the optic chiasm. The patients underwent purely endoscopic endonasal, transsphenoidal resection of their pituitary adenoma by a single surgeon (ARD). The surgical technique is described in detail elsewhere and is beyond the scope of the current article [5].

The technique of sellar reconstruction is briefly described, as it could influence the postoperative MRI interpretation. In cases with no CSF leak during the surgery, the sellar floor was reconstructed using one layer of Surgicel (Ethicon, a Johnson and Johnson Co.Somersville, NJ), followed by multiple layers of Gelfoam (The Upjohn Company, Kalamazoo, MI) and Evicel (Ethicon, a Johnson and Johnson Co. Somersville), classified as a Type I reconstruction. A Type II reconstruction consisted of one layer of AlloDerm (LifeCell Corp., Branchburg, N.J.) positioned flush to the sellar floor, followed by a Type I reconstruction. Type II reconstructions were used in cases where a minute CSF leak was encountered which subsided intraoperatively. If an intraoperative CSF leak was significant, i.e. not subsiding, a Type III reconstruction was achieved. This consisted of a combination of Avitene (Davol, a Bard Co. Warwick, RI) and Surgicel (Ethicon, a Johnson and Johnson Co. Somersville) used to cover the specific area of leak, followed by subcutaneous fat graft, taken from the lower abdominal wall, inserted inside the sella. Next, a thin layer of AlloDerm was used to cover the sella, flush with the bony landmarks, followed by layers of Gelfoam and Evicel.

In recurrent pituitary adenoma cases, if the septum had not been damaged by previous surgery a nasoseptal flap was routinely harvested, as described by Haddad et al [8]. Similarly, in most large and giant macroadenomas (>3.0 cm) a nasoseptal flap was harvested and used for the reconstruction. If a CSF leak was observed at surgery, fat graft and AlloDerm were used prior to placing the nasoseptal flap on the bony surface of the sellar floor, classified as a Type IV reconstruction. A lumbar drain was not placed unless the reconstruction was deemed unsatisfactory, such as a lack of adequate nasoseptal flap (in recurrent pituitary adenomas) or if the CSF leak was viewed as significant by the senior author (e.g. large opening of the diaphragma or third ventricle in giant macroadenoma).

All patients underwent MR imaging on POD#1 and at 3 months following surgery. The MR studies were performed initially on a 1.5T unit and then on a 3T unit as of March 2011. Typical T1-images (TR 500/TE 20) pre and post gadolinium (Gd-DTPA, 0.1 mmol/kg of body weight) administration on the 1.5T unit were obtained in the coronal, axial and sagittal planes, with 3.0mm slices with no spaces. Similarly, coronal, axial, and sagittal T1 pre/post gadolinium images were acquired with 2.5 mm slices using no space on the 3T unit.

Correlating operative reports with POD#1 imaging, early postoperative sellar contents were considered to represent implanted materials including nasoseptal flap whenever used, the re-expanded normal pituitary gland, and/or post-operative blood product. Special attention was made to identify the pituitary gland, pituitary stalk and its deviation, contrast enhancement, and residual tumor. The enhancement pattern of postoperative sellar content was analyzed and three different categories were identified: No enhancement (except for normal enhancement of residual pituitary gland), nodular enhancement (beyond the pituitary gland indicative of residual disease) and linear enhancement (non tumoral, mostly the edge of diaphragma sella or cavernous sinus). The same criteria were used to examine the imaging at 3 months postoperatively.

Postoperative MR imaging alone was used to confirm the absence/presence of residual nonfunctional pituitary adenoma. For functional adenomas, both endocrine panel and postoperative MRI were considered for definition of residual disease.

Pituitary hormonal assay was performed postoperatively on day 1 in all patients and patients were followed-up at Geisinger neuroendocrine clinic at 3 months and 1 year. Any new endocrine deficit was managed according to neuroendocrine standards of care. All patients requiring preoperative visual fields subsequently had postoperative formal neuro-ophthalmological examination at 3-4 weeks following surgery.

Review process:

There were two sets of observers. The first set was the treating team, consisting of a neurosurgeon and a neuroradiologist who possessed all the relevant surgical information and reviewed the post-operative MRIs. The second set consisted of a second neuroradiologist who independently reviewed the MRI findings and was blinded to surgical technique and material used. The review was performed using a workstation to allow interactive interpretation and comparison. The following parameters were assessed:
1) Pituitary gland and its enhancement, 2) pituitary stalk and its deviation, 3) nodular enhancement (residual tumor) or linear enhancement (non-tumoral) and 4) reconstruction/packing materials. Findings were compared to the MRI at 3 months and any discrepancy in interpretation was identified and recorded. Interobserver agreement was evaluated whenever possible.

Statistical Analysis

The sensitivity, specificity, and positive and negative predictive values of POD#1 MRI with respect to 3 month MRI in regards to identification of normal pituitary gland, pituitary stalk and any residual tumor were assessed whenever possible, based on the first observer team findings (neurosurgeon and neuroradiologist). Kappa index was used to assess the agreement between the two observer sets. A kappa value of 0 indicated a level of agreement that would be expected strictly on the basis of chance, whereas a value of 1.00 indicates perfect agreement. With regard to positive kappa value, the following interpretations are generally accepted: slight agreement 0.01 to 0.20, fair agreement 0.21 to 0.40, moderate agreement 0.41 to 0.60 substantial agreement 0.61 to 0.80, and almost perfect agreement 0.81 to 0.99. To measure the kappa index, all cases were evaluated, and a probability value of 0.05 or less was set as statistically significant

RESULTS

Of the 64 patients studied, histology confirmed that 59 patients harbored pituitary adenomas, four had Rathke's cleft cysts, and one patient had a schwannoma. Fifty three of the 59 adenomas were macroadenomas with 12 demonstrating cavernous sinus invasion on MRI prior to surgery (Table 1). Forty three of the 59 adenomas were nonfunctioning while the remaining 16 patients had hormonally active pituitary adenomas. Five patients had growth

hormone (GH) secreting adenomas, 8 patients had prolactinomas (PRL), and 3 had adrenocorticotrophic hormone (ACTH) secreting adenomas (Table 2). In coronal imaging, tumor size ranged from 0.5 cm to 5.2 cm (average size was 2.1 cm). Ten patients had prior, remote, microscopic transsphenoidal surgery either at our institution or at another facility.

Surgical results:

To decrease the risk of post-operative cranial nerve palsy, the cavernous sinus involvement by pituitary adenomas was not directly surgically addressed unless for gentle exploration of the medial wall of the cavernous sinus, however 1 out of 12 patients with cavernous sinus invasion preoperatively had no convincing residual mass on post-operative imaging at day 1 and 3 months. In the 52 patients without cavernous sinus invasion gross total resection of was achieved in 49 out of 52 (94%) patients. Thirteen patients underwent Type IV reconstructions (nasoseptal flap). In 6 of 10 patients with recurrent tumors and in 7 patients with very large or giant macroadenoma a nasoseptal flap was harvested and used during the reconstruction.

In 24 patients, there was evidence of intraoperative CSF leak. Therefore, a Type II (7 patients), III (10 patients), or Type IV (7 patients) reconstruction were performed, as previously described in the surgical technique. Six patients had immediate post-operative lumbar drainage, ranging for 3- 5 days.

In patients with functional adenomas, remission was achieved in 2 of 5 GH secreting adenomas (normalized IGF-1 and Oral Glucose Tolerance Test), in 7 of 8 prolactinoma patients (Prolactin < 20 µg/L with no medication), and in all 3 of the Cushing 's disease patients (normal 24h urinary free cortisol and very low < 5 ug morning free cortisol). The persistent disease in GH adenoma patients was due to cavernous sinus invasion and was addressed by radiosurgery and octreotide acetate in one patient, and by octreotide acetate alone in the other two. Cavernous sinus invasion in the non-cured prolactinoma patient was addressed with radiosurgery and continuation of dopamine agonist treatment.

Eleven patients had some evidence of hypopituitarism in one or several axis prior to surgery; 5 of them had improvement in one or more axis following surgical removal of the adenoma. There were 3 (4.7%) new anterior pituitary deficiency which needed hormone replacement. Diabetes insipidus ensued in 13 patients but resolved spontaneously in 9 and necessitated short term DDAVP administration in the remaining 2. The other 2 patients were continued on DDAVP at 3 months follow-up despite preservation of posterior pituitary gland on MR imaging.

A postoperative CSF leak occurred in 5 patients (8%) after surgery and resolved in 4 after lumbar drain placement. One patient needed re-exploration for further packing and sellar reconstruction. One patient developed clinical meningitis which responded to antibiotic treatment.

One patient with acromegaly developed a new abducens nerve palsy following resection of tumor attached to the cavernous sinus. Another patient developed an oculomotor nerve palsy

following surgery which resolved during the patients hospital stay. No other new cranial nerve deficit was noted.

One patient required removal of implanted reconstruction material one year after complete resection of pituitary adenoma for continued sinus drainage despite several courses of antibiotic therapy. There were no other new neurological complications.

Postoperative Day (POD) #1 MR Imaging

The pituitary gland and the position of stalk could both be identified on POD#1 MR imaging in all cases. Eleven of the 12 patients with cavernous sinus invasion exhibited cavernous sinus involvement on POD#1 MRI. The cavernous sinus part of the tumor in one patient might have either been resected during gentle manipulation and suctioning of the tumor from the medial cavernous sinus wall or the tumor had only significant impingement rather than true invasion of the cavernous sinus (Fig 1). Two patients MR imaging, without cavernous sinus invasion, demonstrated nodular enhancement, suggestive of residual disease agreed upon by both observer sets. One patient had both cavernous sinus and suprasellar nodular enhancement, suggestive of retained tumor agreed upon by both observers (Fig. 2). No other convincing residual tumor was seen on MR imaging in the remainder of patients by either observer set. There were twelve patients with some linear enhancement at the edge of the diaphragm sella or medial wall of the cavernous sinus which was not considered as tumoral enhancement by either observer set. The reconstruction/packing material was clearly distinguishable from the pituitary gland and the stalk in 54 patients. Gelfoam was very hypointense and the fat graft was hyperintense in T1 when used. The nasoseptal flap which enhances with contrast was appreciated outside the sella and was easily distinguishable in all 13 cases in which a flap was used (Fig. 3).

In the other 10 patients where the reconstruction/packing material was not clearly distinguishable, there was some T1 isointense materials inside the sella which were hypointense on T2, and most likely represented postoperative blood products alone or in combination with packing materials. Despite assumption of complete resection in these 10 cases by the treating team (neurosurgeon and neuro radiologist) based on surgeon impression during the operation, close attention was paid to carefully evaluate the suspicious area at 3 months post-operative MRI. However, the second observer considered possible residual tumor in 3 of these 10 patients, while the first observer considered residual tumor in 1 patient.

The kappa values extracted from the interobserver analysis for agreement between observers with regard to identification of normal pituitary gland and the pituitary stalk was 1. Same analysis for identification of residual tumor and packing/reconstruction material on POD# 1 was 0.83 and 0.72, respectively. These values confirmed near perfect and substantial agreement, respectively.

Delayed postoperative MR imaging at 3 months

The pituitary gland, position of stalk, and nasoseptal flap could again be identified on MR imaging in all patients. In 11 patients, residual tumor was again seen in the cavernous sinus.

Of the three MRI's on POD#1 that exhibited nodular enhancement, all three confirmed residual disease on follow up imaging by both observers. The three patients who has suspicious enhancement suggestive of residual disease by the second observer on POD # 1 MR imaging, two of these patients showed no nodular enhancement at 3 months, agreed upon by both observer sets. The third patients MRI showed minimal enhancement along the right lateral margin of the cavernous sinus, believed to be non-tumoral linear enhancement by first observer but not the second observer (Fig. 4). No patients with residual disease required reoperation, determined by the senior author, due to either minimal residual or belief that reoperation would not result in greater tumor removal secondary to the operose location of the residual. Both observer sets agreed that the linear enhancement seen in 12 patients on POD#1 MRI disappeared in 5 patients at three months and remained stable in the other six. In one patient there was a discrepancy between observer 1 and 2 with regards to linear enhancement, the 1st observer disagreed there was linear enhancement. The shape of the pituitary gland, and the position of the stalk, had changed in 7 patients, this however did not interfere with confirmation of gross total resection of the adenoma.

The reconstruction materials (Gelfoam, Evicel and/or fat graft) had partially resolved in 32 patients, completely resolved in 22 patients, and had no resolution in 10 patients. The nasoseptal flap was avidly enhancing in all 13 patients with the flap at 3 months (Table 3).

The sensitivity and specificity for residual tumor detection by MR imaging on POD#1 compared to 3 month MRI were 100% and 97.9%, respectively. The positive and negative predictive values were 94.8% and 100%, respectively. In other words, individuals with a negative test at POD#1 have a 100% chance of having a negative at month 3.

The kappa values extracted from the interobserver concordance analysis for agreement between observers with regard to identification of normal pituitary gland and the pituitary stalk was 1. Same analysis for identification of residual tumor and packing/reconstruction material on 3 month was 0.87 and 0.64, respectively. These values confirmed near perfect and substantial interobserver agreement, respectively.

DISCUSSION

MR imaging following transcranial resection of most supratentorial neoplasms is obtained within 24-48 hours [1, 4, 10, 14, 18]. During this period, the inflammatory process is in its initial stages and implanted materials, such as Surgicel and Gelfoam, have not yet degraded allowing them to be readily identified radiographically. Additionally, blood which has collected within the tumor bed has not yet formed methemoglobin, which is bright on T1 MR imaging, and less likely to be mistaken for residual tumor [10, 14, 18].

Endoscopic endonasal surgery has become an attractive method for the resection of sellar and suprasellar lesions due to improved illumination and visualization [3, 10]. It offers an excellent exposure for tumors located in areas where surgery is typically arduous, such as the cavernous sinus, posterior clivus, and firm tumors located in the suprasellar cistern, although most residual tumors are found in these areas [23]. Several reports in the literature describe the difficulty

interpreting MR imaging following transsphenoidal surgery, due to packing materials and operative changes [6, 20, 21] . Therefore, immediate post-operative imaging following endoscopic transsphenoidal surgery is not typically obtained [6, 20, 21].

Our study demonstrates that MR imaging of the sella/pituitary gland performed on the first postoperative day (POD#1) is just as effective at detecting residual disease as the MRI performed at 3 months following endoscopic endonasal resection of pituitary adenomas with a sensitivity and specificity 100% and 97.9%, respectively.

We found that the pituitary gland and the position of stalk could both be identified on POD#1 MR imaging in all cases. Furthermore, the positive and negative predictive values, with respect to identification of any residual tumor, were 94.8% and 100%, respectively. Reconstruction materials could clearly be identified on POD #1 MR imaging in 54 of the 64 patients as well as identification of all 13 nasoseptal flaps. The Kappa index, evaluating interobserver agreement, for detecting nodular enhancement (residual tumor) on POD#1 imaging was 0.83, indicating near perfect agreement.

While continued or recurrent hypersecretion of hormones suggests residual or recurrent lesion in hormonally active tumors, this does not determine persistent tumor in nonfunctioning pituitary tumors [4, 7, 10]. Therefore, follow up imaging serves as the determinant for residual or recurrent disease. Early imaging facilitates a baseline for evaluating recurrent disease as well as offers the potential for an immediate reoperation before the development of adhesions, and ultimately a chance for remission.

Few studies have addressed early postoperative imaging following transsphenoidal resection of pituitary tumors. Dina et al. studied the appearance of the pituitary gland and sellar contents on postoperative MR imaging, ranging from days 2 through 8, following transsphenoidal resection of a pituitary tumors in 10 patients. The authors studied height of the pituitary mass, relationship to the optic chiasm, enhancement, visualization of the pituitary gland and stalk, and the appearance of the surgical packing within the sella and sphenoid sinus. The authors concluded the immediate post-operative MR imaging following transsphenoidal resection of pituitary adenomas can be misleading.

Rodriguez et al. examined 16 patients MR imaging at 1 week, 1 month, 4 months, and 1 year following the transsphenoidal resection of pituitary adenomas. Contrary to Dina et al, they noted that in all cases 1 week MRI showed the volume of the packing was less than previously demonstrated tumor. Therefore, they deduced that the presence or absence of residual tumor, as well as packing material, could be visualized in all cases at 1 week. These findings where confirmed by later MRI in all patients.

Yoon et al prospectively studied 83 patients following transsphenoidal resection of pituitary adenomas, to determine if early post-operative MRI could differentiate residual tumor. All patients had MR imaging within seven days after surgery. They authors found that 22 patients had nodular enhancement, suggestive of residual disease. These 22 patients had confirmed residual disease either by follow up hormonal assay, reoperation, or by subsequent follow up MR imaging. The authors concluded that the sella retains its preoperative volume on

immediate imaging, allowing early postoperative MR imaging to identify residual tumor from normal gland and implanted materials. Similarly, Kilic et al prospectively evaluated 80 patients after undergoing transsphenoidal surgery. All patients had MRI examinations within 24 hours and then at 3, 6, 9 months and 1 year. They found that MRI performed within a day of transsphenoidal surgery for adenoma removal provides reliable information on the presence of residual tumors.

While both Yoon et al and Rodriguez studies performed early postoperative MR imaging neither performed their studies within 24 hours post resection. None of the aforementioned studies used a pure endoscopic endonasal approach for resection of the tumors Our study supports this data indicating that POD#1 MR imaging is just as effective at detecting residual adenoma as MR imaging performed at 3 months following endoscopic transsphenoidal surgery with a sensitivity of 100% and a specificity of 97.9%.

Upon detection of residual tumor the treating physician is left with several treatment options: observation, medical management, stereotactic radiosurgery, and/or repeat surgery [2]. Multiple reports support the use of stereotactic radiosurgery for treatment of residual disease as it avoids the complications of repeat surgery [2, 11, 15, 19]. However, this is not the optimal treatment for patients with residual chiasmatic compression, and for those who wish to avoid the risks of radiation including hypopituitarism [2]. Benveniste et al. found repeat transsphenoidal surgery to be a safe and effective treatment option in their series of 96 patients who had recurrent or residual pituitary adenoma [2]. Furthermore, they found that repeated transsphenoidal surgery remains the best option for patients with residual or recurrent tumor close proximity to the optic apparatus. Repeat surgery avoids the risk of radiation induced optic neuropathy, a potential complication [2, 11, 15, 19]. Furthermore, repeat surgery is best performed immediately after the index procedure while there is no scar tissue or postoperative fibrosis.

Immediate postoperative MR imaging offers the potential for early management if significant residual disease is present, unlike standard delayed imaging. Similarly, intra-operative MRI can be used as an adjuvant to determine immediate residual disease, however we do not use this at our institution [22]. Patients found to have recurrent or residual hormonally active pituitary adenomas, early MR imaging can provide a potential opportunity to localize the residual and prepare for an immediate second operation before the development of fibrosis and adhesions at the operative site. Furthermore, early MR imaging of nonfunctional adenomas, where hormonal studies cannot be used to determine active disease, allows evaluation of the degree of tumor resection and serves as a baseline study for future comparison for any potential recurrent tumor growth. Although some residual adenomas can descend with time from the suprasellar space to the pituitary fossa, the immediate MR can identify any residual early after surgery. Similarly, early assessment of residual or recurrent disease, as well as identification of the anatomical location of the pituitary gland, is paramount if stereotactic radiosurgery is being contemplated.

Additionally, situations arise where the surgeon encounters difficulty in total resection due to adherence to diaphragm sella or presence of fibrotic tissue (especially in recurrent cases).

It is intuitive to perform postoperative imaging immediately to allow the surgeon to assess the operative resection in reference to what was observed intraoperatively. We found the immediate imaging extremely helpful in this regard. Delaying postoperative imaging for 3 months, attenuates surgeons' recollection of specific intraoperative findings and possible difficulties encountered during the resection. Although careful review of the operative report is always possible, the surgeon will greatly benefit from MRI done immediately after surgery and can assess the resection and the exact circumstances which led to surgical outcome at hand.

Moreover, postoperative day 1 MRI allow the physician to immediately inform the patients regarding the quality of resection as well as further management implications as opposed to conventional 'wait and see' approach until 3 month postoperative imaging is obtained. Also, immediate postoperative imaging becomes beneficial in training residents and fellows in endoscopic endonasal pituitary surgery, as immediate imaging is invaluable for their assessment in correlating intraoperative findings to post-operative surgical results.

Finally, POD#1 imaging allows the surgeon to evaluate the level of resection before the patient leaves the hospital. This becomes beneficial at many centers performing endoscopic endonasal pituitary surgery, where a significant number of patients travel long distances for care. Early confirmation of extent of resection, especially nonfunctional adenomas, can prevent early follow up and the need for additional travel.

While no patients in our series had significant residual disease, early MR imaging resulting in significant residual tumor would have compelled us to reoperate. Without early imaging there is no way, in nonfunctioning adenomas, to assess residual or recurrent disease and early assessment allows for an immediate potential reoperation before the development of adhesions at the operative site. Furthermore, we would have reoperated on functional adenomas not in remission, if the residual was unexpected and not found in the cavernous sinus. Ultimately, we found in our series that our reconstruction technique did not interfere with the interpretation of postoperative MR imaging. Our results suggest that one could therefore consider the timing of postoperative imaging of pituitary tumors comparable to other CNS tumors and follow the same approach of immediate postoperative imaging.

CONCLUSION

Our study demonstrates, based on the first observer set, that immediate MR imaging performed POD#1 following endoscopic endonasal transsphenoidal resection of pituitary adenoma provides accurate and reliable information regarding the presence of residual pituitary adenoma compared to normal pituitary gland, pituitary stalk, reconstruction and packing materials. This information will allow treating physicians to advance the patient's plan of care more expeditiously if indicated, while leaving the option of performing MR imaging again at 3 months if the results of POD#1 imaging are unclear. Immediate postoperative MRI should be strongly considered after endoscopic resection of all pituitary adenomas.

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Figure Legends

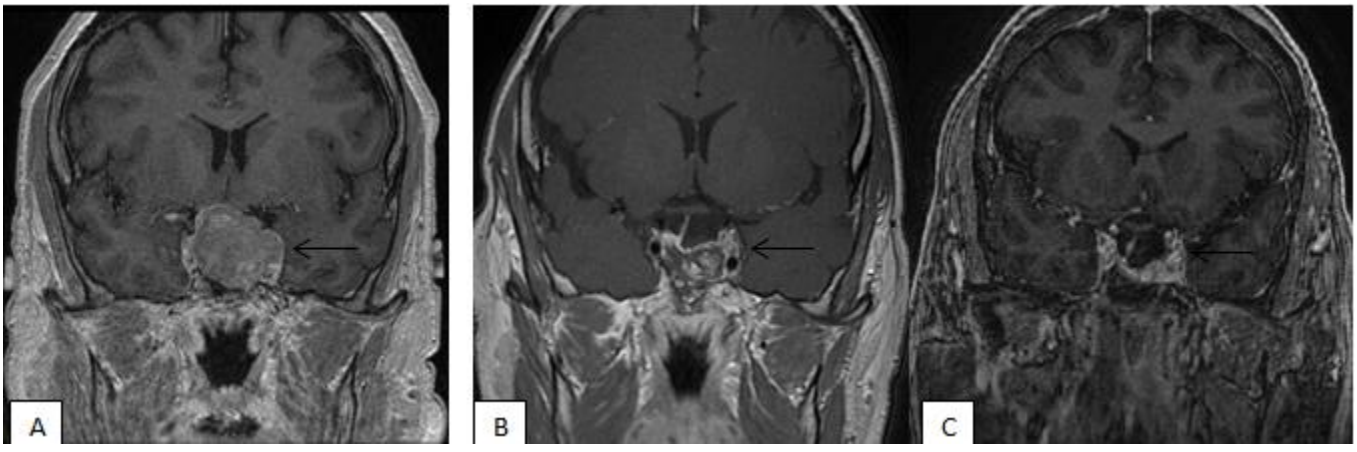

Figure 1: Contrasted MR images in coronal plane

A. Preoperative image of the sella shows pituitary tumor with suprasellar extension compressing the optic chiasm and left cavernous sinus involvement (arrow)

B. Immediate postoperative day 1 image shows normal cavernous sinus enhancement with no appreciable residual tumor (arrow)
C. 3 month MR imaging, shows normal cavernous sinus enhancement with no nodular enhancement of the left cavernous sinus

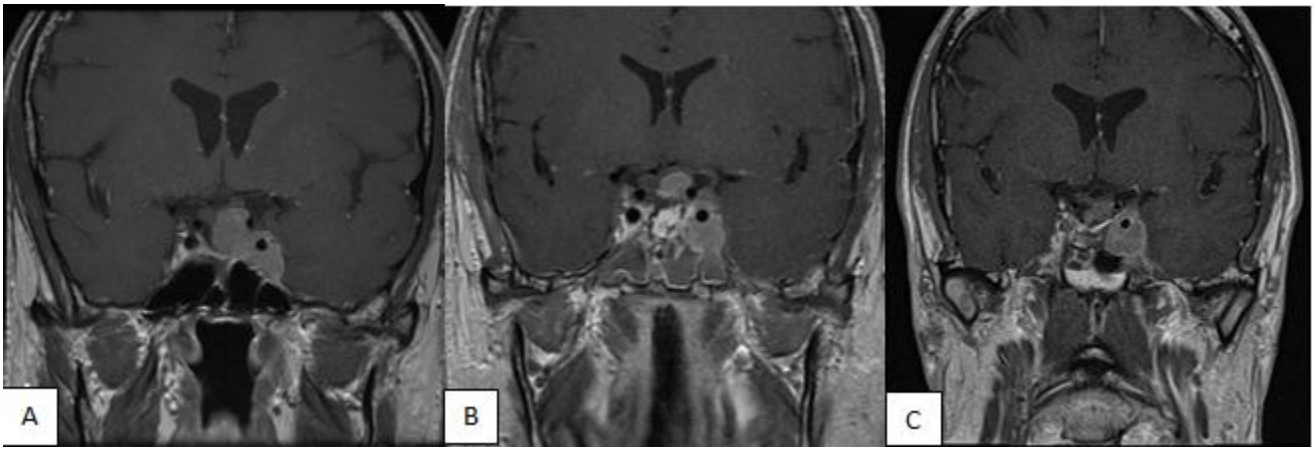

Figure 2: Contrasted MR images in coronal plane

A. 61 year old male with invasive pituitary adenoma with prior resection in 2008 with recurrence
B. Postoperative day 1 image, both cavernous sinus and suprasellar nodular enhancement, suggestive of retained tumor.
C. 3 month MR imaging, again showing retained cavernous sinus and suprasellar tumor.

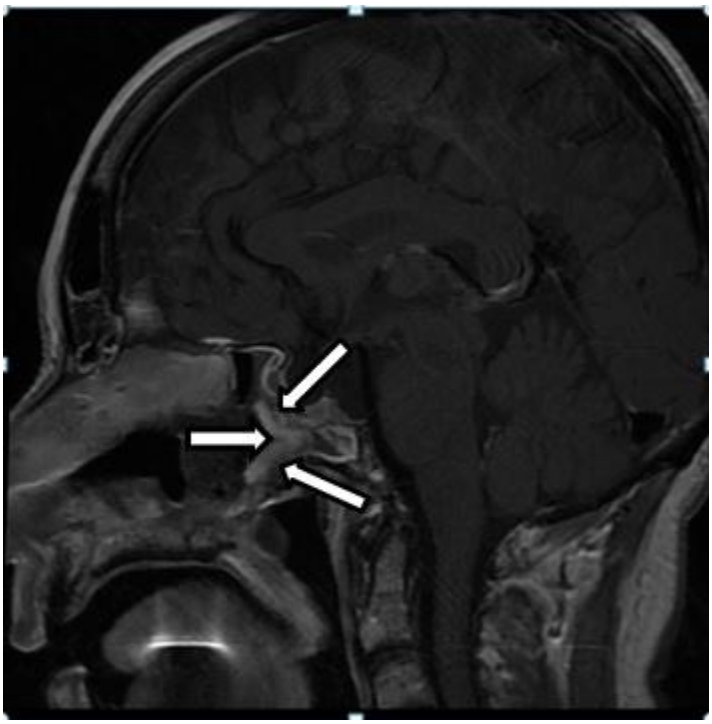

Figure 3: Contrasted MR image in Sagittal plane
Postoperative day 1 MR image showing enhancement of nasoseptal flap (arrows)

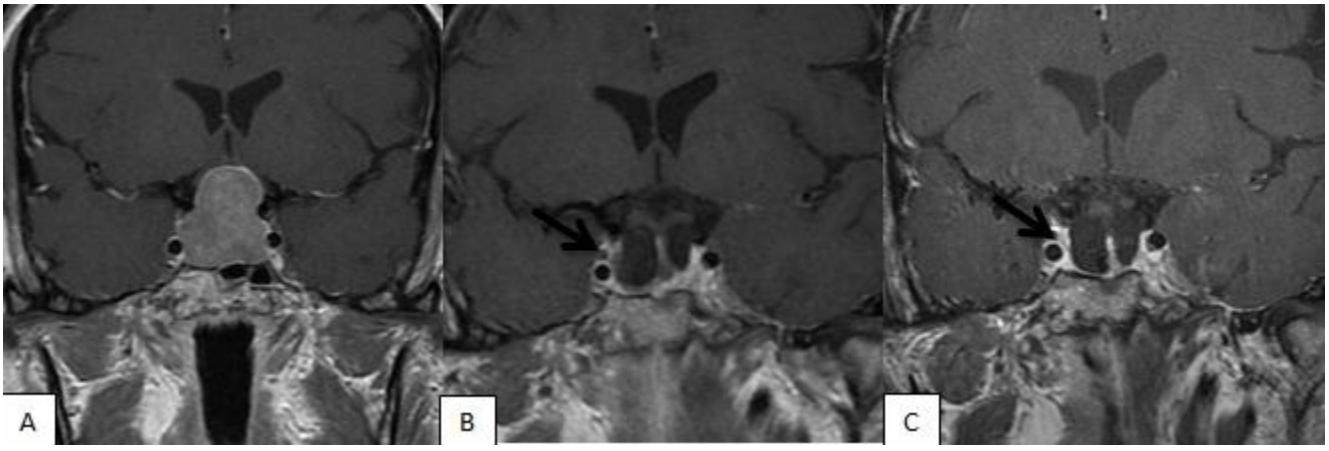

Figure 4: Contrasted MR images in coronal plane

A. Preoperative MRI showing enhancing sellar mass with suprasellar extension
B. Immediate POD#1 image with arrow showing area of believed nodular enhancement, suggestive of residual tumor (arrow)
C. 3 month MR imaging, showing right cavernous sinus linear enhancement (non-tumoral) agreed upon by both observers (arrow)

TABLE 1
Data for 64 endoscopic transsphenoidal surgeries

Characteristic	**No. of Cases (%)**
Average tumor size (range)	**2.1 cm (0.5-5.2)**
histology	
Pituitary adenoma	**59 (92.2)**
Rathke cleft cyst	**4 (6.3)**
Schwannoma	**1 (1.6)**
cavernous sinus invasion	**12 (18.8)**
repeat surgery	**10 (15.6)**

TABLE 2
Data for 59 pituitary adenomas

Characteristic	**No. of Cases (%)**
Nonfunctioning	**43 (72.9)**

Hormonally active	
Prolactinoma	**8 (13.6)**
Growth hormone	**5 (8.5)**
Adrenocorticotrophic	**3 (5.1)**

Table 3

Data for 64 patients MRI after Endoscopic Endonasal Surgery based on the first observer set

	POD # 1	3 Month
Nodular Enhancement (non cavernous)	4	3
Cavernous sinus residual tumor	11	11
Linear Enhancement	12	5
Pituitary gland	64	64
Pituitary stalk	64	64
Reconstruction material	54	22 (32 partially)

Correlation of contralateral subdural hygromas collection with age after craniectomies in traumatic brain injuries

Arrowhead Regional Medical Center
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Introduction

Traumatic brain injury (TBI) is a leading cause of mortality and morbidity in the world (1). From the acute medical standpoint, the treatment of TBI mostly revolves around prevention of secondary brain injury that occurs after the initial insult. Control of intracranial pressure and decompression from a hematoma are frequent reasons for surgical intervention.

Decompressive craniectomy (DC) is a means by which the skull is removed in order to allow space for the edematous cerebrum to herniate outwards, as opposed to herniating inwards towards the brain stem. This effectively removes pressure on the brain stem and increases survival.

DC, however, does pose its own risks that have been reported in the literature. The most common risk factors of DC are the development of subdural hygromas (SH) and hydrocephalus (HCP). Subdural hygroma development after DC has been reported to be 30-70% (2-7). The risk of hydrocephalus development has been reported to be approximately 20-50% (2-5). The literature consistently reports that the HCP develops after evidence of SH at a rate of approximately 50% (2-10). The development of HCP can occur up to 3 weeks after DC (8) and is also reported to occur after cranioplasty as well. Therefore it is imperative that these patients be followed with imaging over a prolonged period of time.

At our institution, we have been realizing similar results as the literature reports in regards to SH and HCP. However, we have also noticed that there are different patterns in SH development. Some occur ipsilateral to the craniectomy site whereas others occur on the contraletral side. A literature search revealed that the incidence of contralateral SH occurs at a rate of approximately 6-7% (8-10). The clinical importance of contalateral SH is that it has a propensity to cause a midline shift and thus a decline neurological status (8). Therefore the risk factors associated with the likelihood to develop contralateral SH are important to consider. However, a literature search on this matter did not reveal any results; thus, raising our curiosity to look into this further.

From a generalized perspective, we have noticed that contralateral SH develops more commonly in younger individuals following TBI and DC. Therefore, we set forth our hypothesis that

individuals younger than 40 years of age have a higher risk factor of developing contralateral SH as opposed to older individuals greater than 40 years of age.

Methods

A retrospective review of all cranial surgeries over the past three years by an individual neurosurgeon a Trauma I institution in Southern California was performed. All of the patients that underwent a craniectomy were then selected. These patients charts and images were then reviewed and the patients that received a craniectomy for traumatic brain injury were then further selected. These patients charts were then carefully reviewed, including all of its imaging. The pathologies that developed, such as subdural hygroma, during the hospital stay were recorded. The subsequent treatment rendered and the follow up imaging were all followed as well.

Results

Analysis was done using IBM SPSS 20 software (IBM, New York, NY, USA). Figures were created with Microsoft Excel 2010 (Microsoft Corporation, Redmond, WA, USA). Nineteen patients met our selection criteria of having needed craniectomy after traumatic brain injury. Of these patients, six were for evacuation of a hematoma related to the traumatic brain injury (32%). Of our sample, thirteen patients were male (68%) and 6 patients were female (32%). Eleven patients (58%) developed subdural hygroma and five patients (26%) developed hydrocephalus and necessitated placement of a ventriculoperitoneal shunt for treatment. A generalized linear model analysis was performed to evaluate the relationship between Age (< 40, ≥ 40), sex (male or female) side of craniectomy (left, right, or bilateral), and side, or occurrence, of subdural hygroma (left, right, or none). The omnibus test is significant implying that some interaction between our three factors (age, sex, and side of craniectomy) and our outcome (subdural hygroma) ($\chi^2(11) = 32.621$, $p = 0.001$). Next, main effects were analyzed and there were significant main effects
noted for sex ($\chi^2(1) = 23.775$, $p < 0.0005$) and the side of craniectomy ($\chi^2(2) = 23.288$, $p < 0.0005$), however, age failed to reach significance as a stand-alone factor on incidence of subdural hygroma ($\chi^2(1) = 2.425$, $p = 0.119$).

Next, interactions of the factors were considered pairwise. Age and Sex combined did not reach statistical significance ($\chi^2(1) = 3.769$, $p = 0.052$). The interactions of age and side of craniectomy ($\chi^2(2) = 29.018$, $p < 0.0005$) and the sex and side of craniectomy ($\chi^2(2) = 19.079$, $p < 0.0005$) did reach clear statistical significance. Unfortunately, likely due to our relatively small sample size ($N = 19$) the three-way interaction of age, sex, and side of craniectomy was not statistically calculable. Certain trends are important to note and will be demonstrated in the subsequent figures.

Figure 1 demonstrates that overall, right craniectomy is more frequent than left-sided craniectomy. Additionally, it is important to note that patients < 40 years old who had right craniectomy were more likely to have contralateral (left-sided) subdural hygroma than ipsilateral

(right-sided) subdural hygroma. Additionally, of the patients < 40 years old who underwent left sided craniectomy, and who developed subdural hygroma, exclusively developed ipsilateral (left-sided) subdural hygroma.

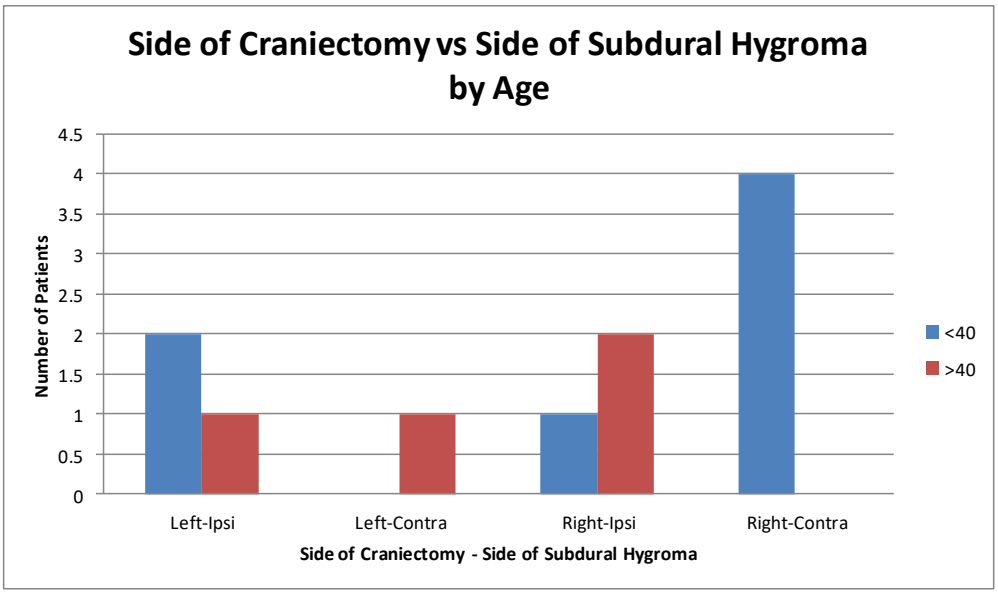

Figure 1: A comparison of patients who developed subdural hygroma after craniectomy. Note that the only patients who developed subdural hygroma on the contralateral side after right-sided craniectomy were < 40 and patients in this age group did not develop contralateral subdural hygroma after left-sided craniectomy.

Figure 2 demonstrates again that only one female patient developed subdural hygroma. It is important to note from this figure that overall, left-sided subdural hygroma is more common than right-sided subdural hygroma. Furthermore, it is of note that men are more likely to develop subdural hygroma after craniectomy than are women regardless of age.

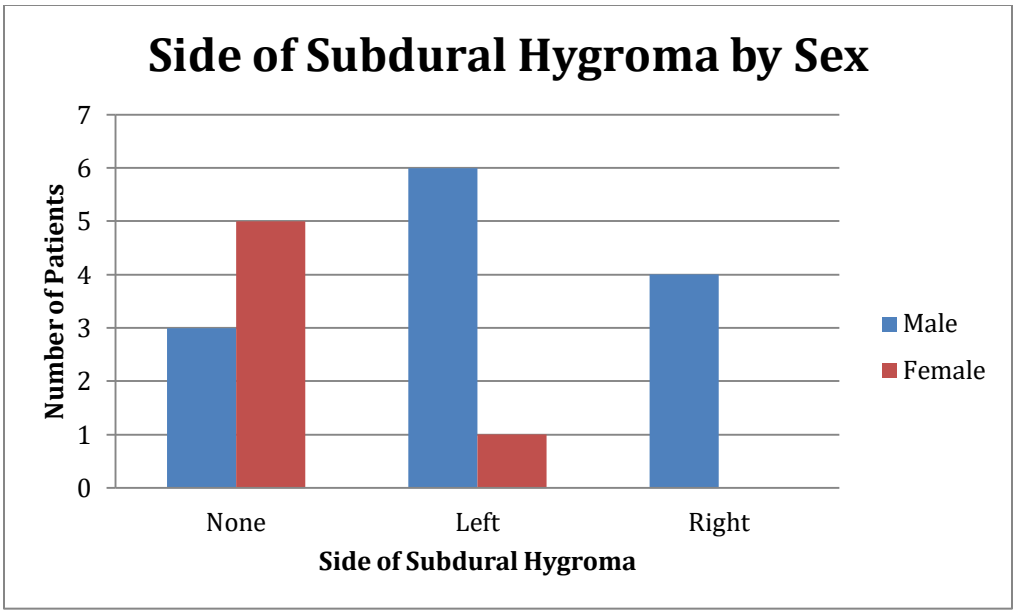

Figure 2: A comparison of the effect of gender as an independent predictor of subdural hygroma after craniectomy. It is important to note that overall, men were much more likely to develop subdural hygroma than were women and that, generally, left-sided subdural hygroma is more common than right-sided subdural hygroma.

Figure 3 demonstrates that bilateral craniectomy patients did not develop subdural hygroma. Additionally, it is important to note than generally, right-sided craniectomy is much more commonly done than left-sided craniectomy. Regardless of the side of craniectomy, left-sided subdural hygroma is more frequent. Finally of note is that right sided craniectomy tends to result more frequently in subdural hygroma on either side than do left-sided craniectomies. This trend, however, was not statistically significant, owing, again, to the relatively small sample size.

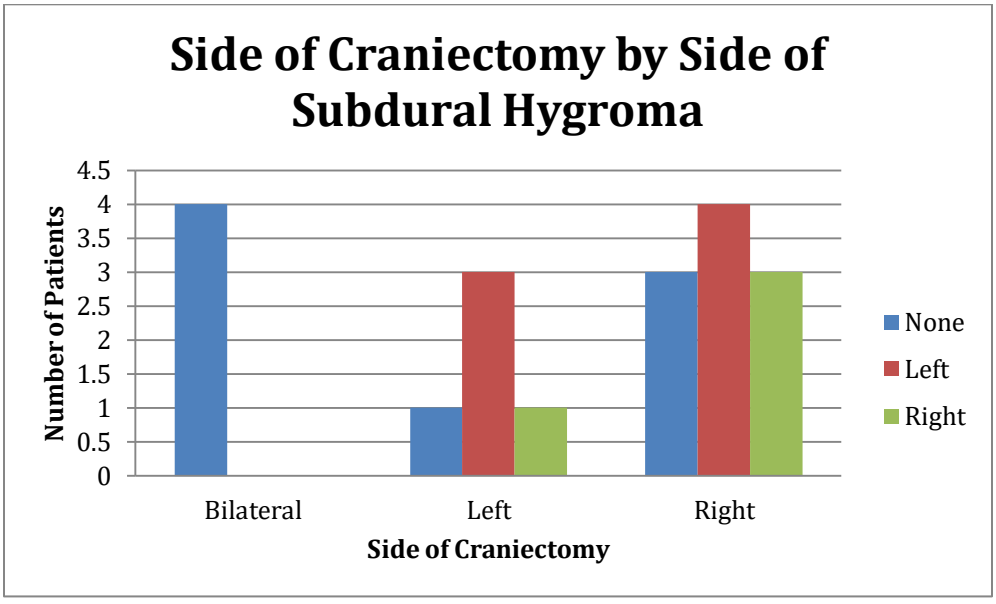

Figure 3: A comparison of the effect of side of craniectomy on the side of subdural hygroma. Of note are that patients who underwent bilateral craniectomy never developed subdural hygroma. Regardless of the side of craniectomy, unilateral craniectomies most frequently resulted in left-sided subdural hygroma. Lastly, right-sided craniectomies tended to result in subdural hygroma more often than did left-sided craniectomies.

Lastly, figure 4 and 4.1 demonstrate a very important age effect – that patients younger than 40 years of age who have had traumatic brain injury requiring craniectomy for decompression are much more likely (31%) to develop hydrocephalus than are older patients (17%). While the comparison of development of hydrocephalus by age-group failed to reach statistical significance in our sample ($F(1,17) = 0.385$, $p = 0.543$), the trend that the under-40 patient group is more likely to develop hydrocephalus than the 40-and-over group is clearly demonstrated in figure 4.The effect specifically demonstrated in figure 4.1, however, is also very important to note insofar as in our sample, formation of sudural hygroma does not seem to be tightly linked with development of hydrocephalus. In the under-40 group, of the patients who developed subdural hygroma, four went on to develop hydrocephalus while three did not and in the 40-and-over group, of the patients who developed subdural hygroma, only one went on to develop hydrocephalus while three did not.

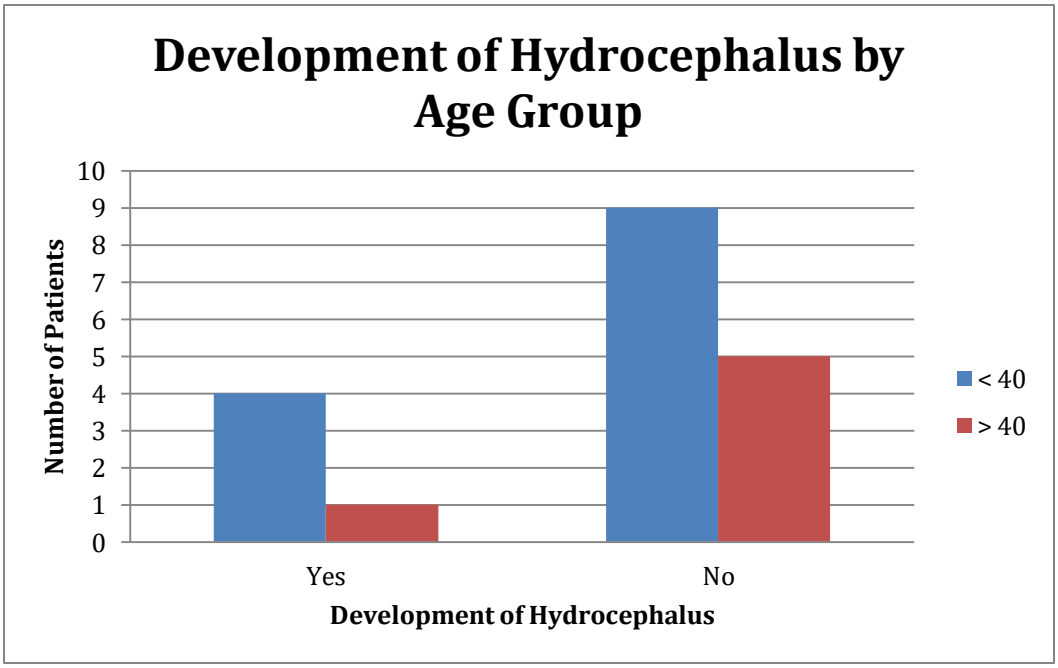

Figure 4: An age-based comparison of whether patients developed hydrocephalus. It is important to note that 31% of under-40 patients developed hydrocephalus overall irrespective of side of craniectomy while only 17% of the 40-and-over age group developed hydrocephalus. This plainly suggests that young age may play a role in the risk of development of hydrocephalus after traumatic brain injury necessitating craniectomy.

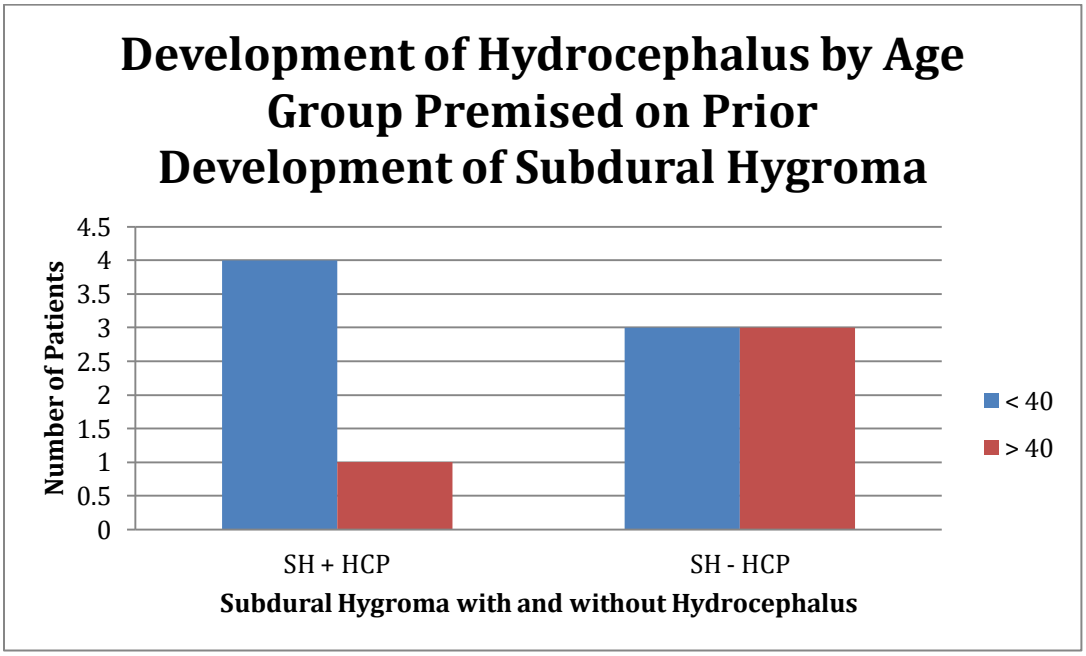

Figure 4.1: This is a comparison by age-group of whether patients who developed subdural hygroma went on to develop hydrocephalus as well. There seems to be no strong relationship between the two. In the under-40 group, seven total patients developed subdural hygroma. Of those, four developed hydrocephalus and three did not. In the 40-and-over group, four patients developed subdural hygroma and of those, only one developed hydrocephalus while the other three did not. Overall, this reminds us that development of subdural hygroma is more prevalent in the under-40 group, but that development of subdural hygroma is not strongly associated with development of hydrocephalus.

Discussion

As mentioned above, our hypothesis was to investigate whether younger individuals less than 40 years of age after traumatic craniectomies have a higher predilection of developing contralateral subdural hygroma than do older individuals. Figure 1 in the results section does indicate a trend towards supporting the hypothesis, but fails to reach statistical significance. We believe that if we had a larger number of subjects in this study, then we would reach statistical significance to support our hypothesis.

There is no known reason as to why this phenomenon occurs but speculations can be made. One reason might be that younger indivduals have certain cerebrospinal fluid dynamics that does not adapt well to sudden changes within the skull's internal environment. Figure 4 and 4.1 support

this idea as it indicates that younger individuals in general have a higher chance of developing SH and/or HCP.

One other result that was surprising is that gender was a significant factor that contributed to development of SH as shown in Figure 2. The results from this analysis did reach statistical significance. This finding and the previous ones from above may suggest that gender specific hormones may be contributing to cerebrospinal fluid dynamics. The fact that male specific hormones are at their peak in the second and third decade of life further correlate with the findings described above. Further analysis indicates that it is probably male hormones that have a detrimental effect on certain changes in cerebrospinal fluid dynamics as opposed to female hormones having a protective effect. (It should be noted that detrimental and protective effect refers to the development of HCP/SH only).

Conclusion

Even though our hypothesis did reach statistical significance, there is a strong trend supporting it. In addition, the idea that male hormones may be an underlying factor leading to higher likelihood of developing SH/HCP is an interesting proposition that will need further investigation. A larger retrospective analysis will be required to further support our hypothesis.

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Profound hypoglycemia presents with reversible symmetrical ADC signal changes isolated to eloquent cortex of the parietal lobe.

Key words: Hypoglycemia; Diffusion signal; Apparent diffusion coefficient

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ABSTRACT

MRI diffusion/ADC signal change with reversal, symmetrically isolated to the cortex of the precentral gyri in profound hypoglycemia has not been previously described. We present a case in which minimal cortical signal change without deep grey matter involvement and subsequent reversal occurred without significant clinical improvement. Correlation of the reversal of diffusion/ADC signal to findings by EEG evaluation has been described in animal studies and not in humans before.

INTRODUCTION

This to our knowledge is the first case report describing MRI diffusion signal change with apparent diffusion coefficient (ADC) reversal, symmetrically isolated to the cortex of the precentral gyri in profound hypoglycemia. Extensive cortical diffusion signal change with or without deep gray matter involvement is identified in hypoglycemic coma. Reversibility of ADC signal change in hypoglycemia has been previously described and has been correlated with varied clinical outcomes. We describe a case in which minimal bihemispheric parietal lobe eloquent cortical diffusion signal change without deep grey matter involvement and with reversal of ADC signal occurred in the context of profound hypoglycemic coma without significant clinical improvement.

CASE STUDY

A 71 year old diabetic female was brought to the emergency room after she was found unresponsive at her nursing home. The patient was on monotherapy for her diabetes (glyburide). An accucheck ® assessment showed a glucose of 32 mg/dl. The patient was given glucagon and D50 with subsequent serum glucose level improvement from 45 mg/dl to 92 mg/dl. This resulted in no change in her level of consciousness.

The neurological exam revealed an obtunded patient with no posturing, no response to tactile stimulation and no spontaneous movement. Her Glasgow coma scale (GCS) was 3 (1= no eye opening, 1= no verbal response, 1= no motor response). She was intubated to secure and maintain an airway. She was normotensive with stable vitals. Her pupils were equal and reactive to light. She had no nystagmus or facial twitching. A day prior to presentation, she was alert,

able to feed herself, and was conversing appropriately with no focal neurologic deficit. Her past medical history was significant for multiple medical comorbidities. This included schizophrenia/bipolar disease, non insulin dependent diabetes mellitus and chronic obstructive airway disease. Laboratory evaluation and a head CT scan without contrast was otherwise unremarkable.

Within one hour of arrival at the emergency department, the patient underwent an MRI of the brain without contrast. This demonstrated bilateral symmetric increased signal within the cortex of the precentral gyri on the diffusion weighted imaging (DWI) sequences. Corresponding signal dropout was identified on ADC mapped sequences. No associated change in signal on FLAIR/T2 or T1 images was identified (Fig. 1 A, B, C and D). The initial MRI study was otherwise unremarkable. A follow-up MRI of the brain was performed approximately 43 hours later. The comparison study showed a diminution in high intensity diffusion signal with a resolution on ADC mapped sequences. No delayed FLAIR /T2 or T1 signal abnormality was noted (Fig. 2, A, B, C and D)

An electroencephalogram (EEG) performed approximately 15 hours after admission showed diffuse slow wave activity of moderate to severe degree consistent with bilateral cerebral hemispheric dysfunction. This was characterized by slow wave activity of 1.5 to 2 Hertz in the frontal central areas. Posterior and central rhythms of 7 Hertz were identified. No epileptiform activity was seen. Five hours prior to the patient's follow-up MRI of the brain, a repeat EEG revealed improvement in the diffuse slow wave activity with higher amplitudes relative to the prior study. In addition some temporal sharp wave activity was noted bilaterally. These findings were consistent with improving encephalopathy associated with hypoglycemia.

Despite rapid correction of the glucose level, she initially remained comatose, intubated and unresponsive. Her clinical status over a total of 19 days post-admission, showed slow and gradual improvements. The patient was weaned of the ventilator after 6 days. After extubation, she began to grimace to painful stimuli and had occasional minimal spontaneous movements of the lower extremities. She had no movement of the upper extremities, even with painful stimuli. At discharge, she was awake and more alert. She was not able to follow commands and made some vocalizations without meaningful conversation. She spontaneously grimaced and opened her eyes. Upon discharge her GCS was 7 (4 = eye opening spontaneously, 2 = incomprehensible sounds, 1 = no motor response). A decision was made by the family to admit the patient to hospice.

DISCUSSION

The clinical presentation of hypoglycemia is non specific and requires early and accurate diagnosis and management for improved outcomes. The varied signs that include anxiety, memory loss, headaches, focal deficits, generalized weakness, seizure and coma are common to

other acute neurologic events such as infarction. Status epilepticus and generalized tonic clonic seizures from other etiologies present with a pattern of cortical diffusion signal change and ADC reversal similar to the case presented and are important diagnoses to exclude in the emergent management setting (1, 2).

DWI and ADC signal changes in severe hypoglycemia have been previously reported in patients with varied and selective involvement of grey and white matter areas (3, 4, 5). Correlation of the location of signal change on DWI/ADC sequences in hypoglycemic patients with prognosis, as well as correlating the reversibility of such lesions with patient outcomes has been suggested by prior case reports and a study by Kang et al (1, 3, 4, 6). Extensive bi-hemispheric cortical lesions with or without basal ganglia involvement is observed in severely affected patients with hypoglycemia (3, 4, 5). In a study of MR imaging features of hypoglycemia, single lobe involvement resulted in complete recovery. This study also identified complete recovery with isolated white matter involvement (1). DWI/ADC signal change with post therapeutic reversal isolated only to the precentral gyri of the parietal lobes in a comatose hypoglycemic patient has not been previously reported. Despite isolated limited cortical involvement of the eloquent brain with ADC signal reversal, the clinical prognosis of such a pattern in our patient was similar to more extensive cortical and or deep grey matter involvement.

The changes in diffusion signal with hypoglycemia occurs initially in the cortex with progressive involvement of the deep grey matter structures and hippocampi (3, 6, 7), where selective vulnerability to disruption of protein synthesis has been identified (5). The time over which diffusion signal change occurs and the level of hypoglycemia that induces these changes in humans is not known. The resultant signal change and neurologic deficit also appears to be specific to the individual. In animal models permanent neurologic deficit was identified in only 73% of cases after a period of 6 hours (8). A recent publication demonstrated no diffusion signal change in non comatose patients subjected to short term hypoglycemia (9). Reported studies have shown reversal of ADC signal change with and without clinical improvement. Clinical recovery with signal reversal was noted in one case report at 10 days and was noted in another case at 22 days post ictus with a poor outcome (3, 4, 5, 6). Our patient's hypoglycemia was corrected within 4 hours of its discovery. The reversibility of the reduction in ADC was demonstrated within 48 hours of the initial MRI.

The mechanism of diffusion signal change in hypoglycemia occurs as a result of cellular membrane sodium potassium pump failure and cellular swelling with extracellular volume depletion, as it does in infarction (3). In infarction however, intracellular acidosis occurs due to hypoxia. Consumption of intracellular metabolic acids with resultant alkalosis is present in hypoglycemia (5). The reversal of ADC signal is an important consideration in excluding infarction. White matter structures affected by hypoglycemia are the internal capsules, corona radiata and the splenium of the corpus callosum. Associated signal change is thought to occur by

a different mechanism, with extracelluar excitatory peptide secretion (glutamate) resulting in glial cell and myelinic sheath edema (1, 3, 5, 7). Involvement of the corona radiata and centrum semiovale occurred in 64% of patients in a study evaluating the imaging findings of hypoglycemia (1). In neonates poor outcomes are associated with involvement of the occipital and parietal lobes (10). Symmetric early phase involvement of the occipital lobes with gradual recovery in adults has been noted (11). Early phase parietal pattern of involvement in adults may also portend a poor outcome as was identified in our case. Occipitoparietal involvement is thought to occur when hypoperfusion complicates hypoglycemia, as these regions are more vulnerable to diminished blood flow (12, 13). Our patient was not hypotensive on presentation to the emergency room.

The duration of EEG isoelectricity correlates with the severity of hypoglycemia. In an animal study looking at the MRI findings after temporary severe hypoglycemia, ADC signal change within the cortex and periventricular regions was identified before EEG isoelectricity. Global ADC signal change was noted with the onset of cerebral isolectricity (7). This corroborates the greater earlier vulnerability to the cortical regions as in our patient, prior to overall brain neuronal dysfunction. Improvement in EEG activity and ADC signal occurs with glucose infusion. In our study, the patient had diffuse slowing of a moderate to severe degree on EEG at 15 hours after admission. Prior to the patient's follow-up MRI and after the patient's glucose had normalized, the EEG showed improvement in slow wave activity with bilateral temporal sharp activity. This appears to correlate with aspects of the animal study. In our study reversal in ADC signal was seen within 5 hours after the EEG showed improvement.

CONCLUSION

DWI hyperintense lesions in hypoglycemic patients not involving the deep grey matter structures, and involving solely the cortex have a better prognosis. Increased diffusion signal with reversal of ADC signal in a hypoglycemic comatose patient with limited eloquent cortical parietal lobe involvement and without significant neurologic improvement has not been previously described. The reversal of ADC signal within 48 hours of the insult also corresponded to commensurate improvement on EEG evaluation as has been seen in animal studies and not in humans before.

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FIGURES

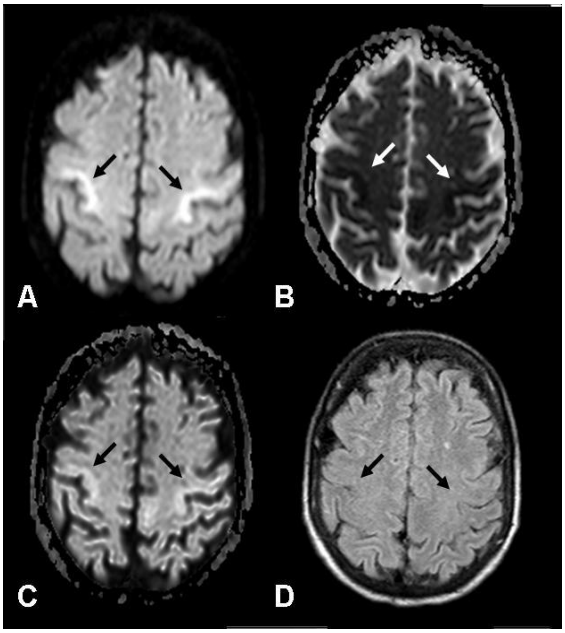

Figure 1

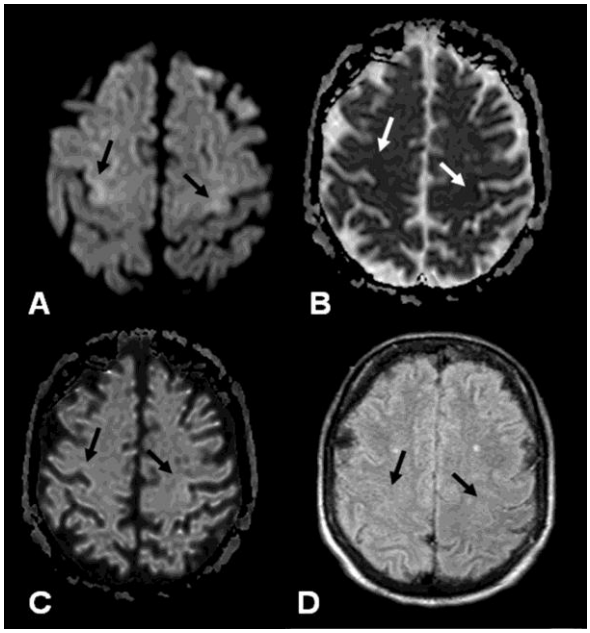

Figure 2

Figure 1: Select axial MR image sequences acquired 4 hours after onset of ictus demonstrating symmetric increased diffusion signal isolated to the precental gyri (A) with corresponding change in ADC (B) and eADC signal (C). No associated FLAIR signal change (D).

Figure 2: Select axial MR image sequences acquired at 43 hours post ictus demonstrating reversal of diffusion (A) ADC (B) and eADC (C) signal in the precentral gyri bilaterally. No delayed FLAIR signal change (D).

"Skate or Die": Depiction of head injury prevention in professional skateboarding media

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Abstract

Introduction: Since inception in the 1950's, skateboard has become increasingly influential and mainstream, especially among adolescent and young adults. This is in part due to the professional skateboarding industry action media and magazines producing independent skateboarding films. With the number of skateboarders and the complexity of skating maneuvers increasing, so too has the risk potential and severity of skateboard associated head injuries increased. In this investigation, we analyzed the prevalence of head injury prevention in professional skateboarding impact in culture.

Methods: A content analysis for helmet use among professional skateboarders was performed by viewing 354 of 2131 independent skateboarding films produced by major skateboarding product companies and prominent skateboarding magazines from 2000 to 2012. An additional 121 short films that were strictly dedicated to skateboarding professional's injuries while skating were also included.

Results: In the analyzed films, there were 564 different professional skateboarders producing a total of 276,527 skateboarding scenes. Street location skating comprised the majority of scenes followed by park skating, and half-pipe skating, being 231,662 scenes (83.8%), 38930 scenes (14.1%), and 5814 scenes (2.1%) respectively. Only 10642 scenes (3.9%) depicted a professional skateboarder wearing a helmet. Helmet use compliance rate was highest in half-pipe location (98.3%), whereas the street location was the lowest (1.8%). Mild to severe head injuries were shown in 794 scenes (0.3%). Scenes containing signs and symptoms of a traumatic brain injury were visualized in 41 (5.2%) of the head injury scenes.

Conclusion: Professional skateboarding media is profoundly absent in promoting helmet use and thus head injury prevention. Although it is unlikely the intent of professional skateboarding films, there is an occult message being conveyed that there is invulnerability to head injuries for the professional skateboarder skill level. We believe the most effective means in improving head injuries among all skateboarder levels is for all professional skateboarders to use helmets while skating, especially during filming and marketing. The skateboarding industry has an obligation to promote safer depictions of this sport.

Introduction

Skateboarding technical maneuvers have significantly advanced since its inception in the late 1950's, as has the sports' popularity. Skateboarding's popularity was a roller-coaster ride from the 1970's through the late 1980's. With the invention of handheld camcorders, skateboarding grew exponentially as skateboard companies, skate shops, and skateboard magazines were able to produce independent films to promote their products. Since the first skateboard video was released in 1976[1], filming and photography have become an integral part of professional skateboarding with thousands of skateboarding industry related films having been

produced[2]. To date there are approximately 5000 sponsored skateboarders by major skateboard companies worldwide and only 250 - 300 active professional skateboarders[3].

The majority of medical professionals have little experience and knowledge of skateboarding in general, which is likely due to multiple factors including its relatively young existence. A concise epidemiological report of skateboarding was published which provides a basic understanding for the medical professional[4]. Skateboard related injuries have been previously studied with head injury occurrence rates reported between 0 – 50.8%[5,6,7,8,9,10,11,12,13,14,15].The severity of skateboard related head injuries was shown to be reduced by the use of a helmet[6,11]. However, helmet utilization among those riding a skateboard was reported as only 7.2% of all injured patients[6]. The U.S. Consumer Product Safety Commission reported that in 2004, 18,743 skateboard related head injured patients were seen in U.S. emergency departments and 764 of those were admitted to a hospital[16].

To become better acquainted with aspects of this study it is important to have a basic understanding of skateboarding films. Professional skateboarding films are most consistent with a documentary type film more than any other genre of film. Typically, however, there is no story line or plot. Skateboarding films generally focus on three main objectives; the skater, the location being skated, and the complexity of maneuvers performed. The film typically begins with an introduction of the skateboard company team's members while the remainder of the film has segments of scenes dedicated to each skater performing different maneuvers in different locations. Each skateboard product company (skateboard deck company, skateboard shoe company, skateboard clothing company, etc…) has a team of professional riders it sponsors and in general produces their own films. Similar to other professional athletes, each professional skateboarder is sponsored by different companies than their fellow riders. It is common to see one rider on multiple different company films. On average it takes between 3 -5 years to produce each film. Each maneuver may take a skater multiple attempts before it is deemed worthy for the final cut. Filming of these maneuvers is mainly done by other professional skateboarders, not by blockbuster professional filming crews or companies.

Locations are also important to understand and include streets/urban areas, skate parks, half-pipes, dry swimming pools, and man-made bowls. When the term "street" is used, it refers to common pedestrian occupied areas which include school yards, business building areas, and other areas with concrete ledges, benches, stairs, and handrails. These street locations are not areas built by a city ordinance solely for skateboarding. A "park" location is an area dedicatedly built for skateboarding by a private company owner or a public city ordinance. Parks often contain similar objects that are found in street locations and often require helmets to be worn in order to enter. Half pipes and bowls are typical found in a skate park but are separate entities from the park. Competitions are typically held in skate parks and half-pipes. Dried swimming pools are also skated locations but typically found in private homeowner areas.

The purpose of this study is to provide a contemporary view on the depiction of head injury prevention in the realm of professional skateboarding media, the potential role

professional skateboarding films play in influencing head injury prevention on non-professionals, and provide head injury statistics for professional skateboarders.

Methods

A content analysis was performed on 354 of 2131 independent films produced by top skateboarding product companies and prominent skateboarding magazines that were released from January 1, 2000 to December 31, 2012. The sample selection also included two of the most influential skateboarding films ever produced, which were released in 1995[17] and 1999[18]. Among the 354 independent films reviewed was a collection of 121 shorts produced by a prominent skateboarding magazine that was dedicated to only failed skateboarding maneuvers resulting in injuries. Two databases which contain listings of professional skateboarding films and one database containing the major skateboard companies were referenced[3,19,20]. Films with the most views of the databases between the two previous mentioned dates were selected for analysis.

Film scenes were eligible for analysis if there was a skateboarder riding a skateboard and attempting a maneuver. Scene variables included the presence or absence of a helmet, location of skateboarding (street, park, or half-pipe), failed attempts of a maneuver resulting in a head injury, presence of a medical facility or medical personnel filmed during the scene, signs and symptoms of traumatic brain injury, and if a skater provided commentary relating to their traumatic brain injury from a scene. A scene was determined as ended after there was permanent cutaway. A head injury was determined positive if the skateboarder was visualized as hitting their head or face. Preventative measures for head injury relate only to those scenes in which a helmet was being worn by the athlete.

Four avid non-professional skateboarders, one of whom is the primary investigator, took part as media coders. Films were viewed together by all four coders so as to discuss and review any discrepancies. Intercoder reliability measure was calculated using an SPSS-macro with a coefficient of >0.90 being achieved for each variable reported.

Results

There were a total of 564 different skaters in the 354 films with a mean of 16 ± 5 skaters per film (Table 1). A total of 276,527 scenes in the 354 films including the 121 injury dedicated scenes were eligible for analysis. The mean number of eligible scenes per film was 781. Mean length of film is 39.21 minutes with the scene length mean of 3.2 seconds. The majority of films dedicated a segment for each skater which mean length of time was 2.51minutes. The 121 short films had a mean length of 45.2 seconds. There were only 2 of these shorts that were compiled as a scene montage (59 scenes in one and 364 scenes in the other) of multiple different skateboarders whereas the 119 other shorts were comprised of only one scene of the same skateboarder.

Table 1: Film Characteristics

Variable	Characteristic
Year of films reviewed	1/1/2000 – 12/31/2012
Number of Films	
Full	354
Dedicated	121
Film Length: Mean	
Full	39.21 min
Skater's segment	2.51 min
Scenes: Total	276,527
Full	275,985
Dedicated	542 (2 montages: 59 scenes and 364 scenes)
Mean per film	781
Scene length: Mean	
Full	3.2 sec
Dedicated	45.2 sec
Skaters: Total	564 different skaters
Per film	16 ± 5

Street location skating comprised the majority of scenes followed by park skating, and half-pipe skating, being 231,662 scenes (83.8%), 38930 scenes (14.1%), and 5814 scenes (2.1%) respectively (Table 2). Of the street scenes, skated areas consisted of straight handrails spanning >10 stairs (30.7%), flatland maneuver (26.5%), gaps > 10 feet (16.9%), ledges/benches/boxes (15.2%), kinked handrails > 10 stairs (10.7%), and other (4%). The majority of skate park scenes consisted of ledges/benches/boxes, transitions, ramps, rails, bowls, and other (23.8%, 23.7%, 21.7%, 15.3%, 11.2%, 4.3% respectively). Half-pipe area scenes consisted mainly of half-pipes (68.9%), super-pipes (19.1%), transitions (10.0%), and full pipes (2.0%).

Table 2: Scene Locations

Location	Scenes	Location	Scenes
Scenes: Total	276,527	Park: Total	38930 (14.1%)
Street: Total	231,662 (83.8%)	Ramp	8448 (21.7%)
Ledge/Box/Bench	35206 (15.2%)	Ledge/Box/Bench	9265 (23.8%)
Rail		Bowl	4360 (11.2%)
Straight > 10 stairs	68792 (29.7%)	Rail	5956 (15.3%)
Kink > 10 stairs	22467 (9.7%)	Transition	9227 (23.7%)
Gaps		Other	1674 (4.3%)
> 10 feet	36828 (15.9%)		
Flatland maneuver	59063 (25.5%)	Vert: Total	5814 (2.1%)
Other	9266 (4%)	Half-Pipe	4006 (68.9%)
		Super-Pipe	1110 (19.1%)
		Full-Pipe	116 (2%)
		Transitions	582 (10%)

Table 3: Helmet Compliance Rate

Variable	Compliance Rate
Helmet Scenes: Total	10784(3.9%)
Location	
Vert	10601 (98.3%)
Park	68 (<1%)
Pool	63 (<1%)
Street	52 (<1%)

Of the 276,527 scenes, only 3.9% (10784 scenes) depicted a professional skateboarder wearing a helmet (Table 3). Helmet use compliance rate was highest in half-pipe location with (98.3%), whereas the street location was the lowest with 52 scenes (<1%). Of the 52 scenes where street skaters wore a helmet, only 2 scenes depicted the helmet being worn properly with the chin strap buckled.

An analysis of head injuries in the 354 films revealed that 223 (63.9%) films had at least one scene present where a head injury occurred (Table 4). A total of 673 (0.2%) of the 276,527 scenes depicted a head injury. The most common head injury occurred in 249 street scenes, followed by 175 park scenes, 141 pool scenes, and 108 vert scenes (37%, 26%, 21%, and 16% respectively). In only 44 (15.3%) head injury scenes was there a helmet being worn. The most common location of helmet use in a head injury scene was in the half-pipe with 32 scenes (73%). Street scenes in which a head injury occurred where a helmet was being worn accounted for only 2% (1 scene) of all head injury scenes. The outcome of that one scene showed no symptoms or signs of concussion occurred to the skateboarder.

Table 4: Head Injury Scenes

Variable	Full Length Film	Dedicated Injury Shorts
Head Injury (at least one per film)	223/354 (63.9%)	98/121 (80.9%)
Head injury scene: Total	673 (0.2%)	98/276,527 (<1%)
Head injury scene per location		
Street	249 (37%)	
Park	175 (26%)	
Pool	141(21%)	
Vert	108 (16%)	
Helmet per head injury scene	44 (15.3%)	14 (14.3%)
Helmet per head injury location		
Vert	32 (73%)	8 (58%)
Park	7 (16%)	3 (21%)
Pool	4 (9%)	3 (21%)
Street	1 (2%)	0 (0%)
Signs and symptoms of head injury	32/673 (4.8%)	9/98 (9%)
Medical personnel	23/276,527 (<0.1%)	4/98 (3%)

The 121 short films dedicated to only injuries by professional skaters showed 98 scenes with a head injury (Table 4). In the 2 montage shorts there were a total of 54 head injury scenes while 44 head injury scenes were shown in the other 119 shorts. Of the 98 head injury scenes only 14 (14.3%) had helmets present. Compliance rates for helmet use in locations where a head injury occurred were the half-pipe 8 scenes, skatepark 3 scenes, pool 3 scenes, and street no scenes (58%, 21%, 21%, and 0% respectively).

Ambulance, hospital, and medical personnel scenes shown were present in < 0.1% of the 354 films and 3.0% of the injury dedicated 121 short films (Table 4). Scenes containing signs and symptoms of a traumatic brain injury such as vomiting, altered level of consciousness, and seizure were visualized in 41 (5.2%) of the total 794 head injuries. Only 11 of those professional skaters who suffered signs and symptoms of traumatic brain injury provided commentary on the scene depicting the head injury. Commentaries provided contained comments regarding intensive care unit stay, requiring intubation, and neurosurgical management.

Discussion

Skateboarding is becoming an increasingly popular sport/activity worldwide and with it increased potential for head injury occurrence. Studies related to skateboarding head injuries have been published[6,7,8,9,10,11,12,13,14,15], however, when compared to other sports the number of studies is significantly low. Of the known skateboard related injury published studies to date, only two studies mention enrollment of self-reported professional skateboarders[12,14]. However, the studies numbers of reportedly enrolled professionals were few. Whether these individuals were truly professionals is unknown as they were self-reported professionals. Furthermore these studies also included BMX riders and inline skaters. Skateboarding is under-represented by the medical profession as is evidenced by the lack of scientific literature published in comparison to other sports.

Studies have shown that professional athletes do influence adolescent behavior, decision making, and loyalty to purchasing and marketing sporting industry brands[21]. Television and blockbuster media messages have also been shown to influence behaviors and actions of its' viewers[22,23,24]. To date there appears to be no studies regarding the influence that professional athletes have on wearing protective gear. Kroncke et al. showed that 45% of adolescent skateboarders reported being influenced to wear a helmet by witnessing or sustaining an injury and the remaining 55% influenced by professional skaters, parents, and peers[25]. Helmet use has been shown to decrease the severity of skateboard related head injuries[6,11]. However, in our investigation we have found that professional skateboarding media poorly depicts head injury prevention. The potential influence that these professional skateboarding films have on viewers can be significantly effective. Evidence for this influence may be demonstrated by non-professional skateboarders who are seeking company sponsorship. Often times these skaters will film themselves attempting to perform the same maneuvers at the same locations seen by professionals in these films.

Helmet compliance rates by professional skateboarders of these films, in particular street riders, are low while compliance rate for vert/half-pipe riders is significantly high (1.8% and 98.3% respectively). The factors related to this are physical appearance and peer opinion, a notion that because street location skating is slower and has lower obstacles it requires less protection than vert skating, and the influence that legendary pioneer skaters had on vert/half-pipe skating in the late 1970's and early 1980's who wore protective gear. It is important for medical professionals to understand that physical appearance and peer opinion are important aspects in skateboarding and in the skateboard industries methods for the advertisement of their skaters. Professional skateboarders that mainly ride street location typically view helmets as a sign of inexperience as well as a burden on their skating and physical style. It cannot be expected that increased helmet utilization by professional skateboarders will change overnight. Helmet use among the major professional sports took adverse events before professional athletes would wear helmets[26]. Whether or not professional skateboarding will follow the same course is yet to be seen.

It is also important to understand that an official governing body in skateboarding does not exist and therefore neither do official rules. City ordinances and private owners often times require helmet use in order to use a designated skatepark, which may improve compliance rates for helmet use. It should be noted that the majority of professional skateboarders do not skate local city skateparks. There are events where professional skateboarders may choose to compete, such as the ESPN X Games, Street League Skateboarding, and Dew tour. However, the majority of professional skaters do not compete. These competitions do have governing bodies, yet they currently allow the skater to choose whether or not to wear a helmet. Each skateboard company however is a governing body for its' own riders and has the potential, as they sponsor each rider and provide the riders monetary source, to influence professional skateboarders to utilize helmets as a part of their personal style.

There are unfortunately leaders in the skateboarding industry who promote head injury prevention for beginning level skaters, yet claim that professional skill level riders seem to be invulnerable to head injuries[27]. Professional skateboarders themselves acknowledge that injury is inherent to skateboarding[28]. Professional skateboarders are susceptible to head injuries which the findings of our investigation provide. Our study, however, has limitations in providing correct statistics of head injuries incurred by professional skateboarders as these films often times do not include footage of injuries that have occurred. Other limitations that exist are that not all skateboarders in these films are professionals, some are sponsored amateurs at the time of an earlier produced film but then become a professional in later produced films.

Conclusion

We conclude that the professional skateboarding media is profoundly absent in promoting helmet use and thus head injury prevention. Although it is unlikely the intent of professional skateboarding films, there is an occult message being conveyed that there is invulnerability to head injuries for the professional skateboarder skill level. We believe the most effective means in improving head injuries among all skateboarder levels is for all professional skateboarders to use helmets while skating, especially during filming and marketing. The skateboarding industry has the potential to influence the use of helmets among their professional and sponsored riders. They also have an obligation to promote safer depictions of this sport. Furthermore, we do not call for a ban of skateboarding or a departure from the skating locations by professional skateboarders but rather that professional skateboarders promote head injury prevention by making helmets apart of their own personal style and thus apart of the skateboarding culture.

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