AMBULATORY SURGERY

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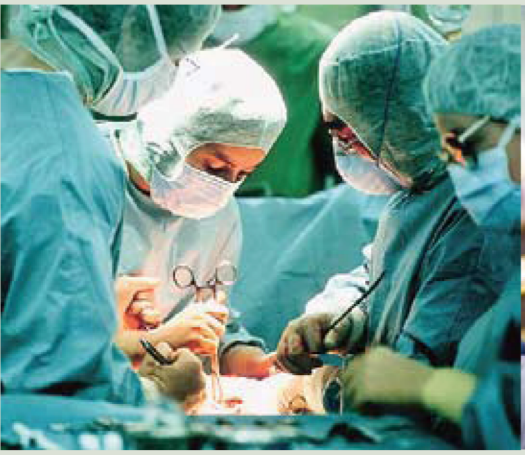


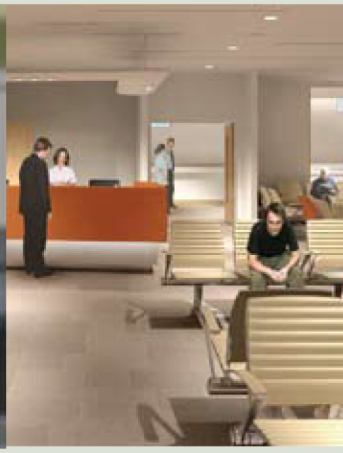

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Editorial

Mark Skues, Editor-in-Chief

Welcome to the 3rd decade of the 21st Century, and to the new edition of *Ambulatory Surgery*. This year promises to be an exciting one, with a forthcoming European Symposium on Ambulatory Surgery in Madrid, now just over a month away from 19th–21st April. If you haven't booked study leave or registered yet, then click on **www.iaascongress2020.com** for all the details. I hope that the next edition will contain the abstracts that were presented at this meeting, but surely, it's better to hear ongoing developments first hand?

In this edition are four papers on diverse subjects related to ambulatory surgery, reviewing a couple of orthopaedically related subjects, pain after ambulatory surgery, and gastric contents in paediatric patients.

Cogan and colleagues have evaluated the potential effects of an intra-articular injection of morphine and clonidine, compared with saline control, in patients after hip arthroscopy. In this paper, they find that there is no analgesic benefit of such an injection when post-operative oral morphine equivalents are compared with the saline control group. It is unusual for this Journal to publish a paper with "negative" results, but it's a tribute to the authors for investigating a modality of care and finding no difference in its use.

Another paper from the United States reviews patient satisfaction in ambulatory shoulder arthroplasty. While this is a relative rare procedure for scheduled day surgery, the authors report on an initial cohort of 29 patients who underwent the procedure with general anaesthesia and an interscalene block. All of these patients were discharged on the same day, with no admissions or emergency room visits during the 90 day post-operative period. Nearly 90% of patients stated they would prefer same day discharge, and 96.5% were satisfied with their procedure and outcome.

Rodrigues and co-workers from Portugal reviewed 24 and 48 hour questionnaires from over 6000 patients to evaluate the incidence of post-operative pain. They divided the groups into the severity of pain experienced, with surgical speciality and type of anaesthesia subgroups, and then followed up with those patients describing uncontrolled pain. They found that uncontrolled pain occurred in 2.2% of the patient cohort, and most commonly in neurosurgery and orthopaedic operations. Strangely, regional anaesthesia attracted one of the higher rates of uncontrolled pain, suggesting that clinical staff may underestimate the need for analgesic advice when the block wears off.

The fourth paper from Japan describes children undergoing ambulatory surgery where pre-operative anxiety was compared with volume and pH of gastric contents. Anxiety was measured both on admission to hospital, and on entry to the operating theatre, while gastric volumes and acidity were measured after induction of anaesthesia. The authors found that larger gastric volumes were found in children with a higher anxiety score on admission to the operating theatre. However, they were able to refute the hypothesis that waiting times in hospital affected anxiety, and had an effect on gastric volumes or acidity.

I hope these synopses encourage you to browse the papers or even contribute to the Journal in due course. In the meantime, I hope to see you next month in Madrid.

Mark Skues
Editor-in-Chief

Intra-articular Morphine and Clonidine Injection after Hip Arthroscopy: A Randomized, Triple-Blind Controlled Trial

C.J. Cogan[a,b], V.K. Tjong[a], K.F. Dunne[a], S Sahota[a], J. Tuttle[a], M.A. Terry[a]

Abstract

Hip arthroscopy is an increasingly common outpatient procedure for which postoperative pain control remains a vital component of patient care and surgical outcome. The objective of this study was to determine the effect of intra-articular morphine and clonidine injection as compared with placebo on postoperative opioid requirement after hip arthroscopy. Seventy patients undergoing primary hip arthroscopy were randomized to receive an 11mL intra-articular injection of 10mg morphine + 100mcg clonidine (study) or normal saline (control) at the conclusion of arthroscopy. The primary outcome was opioid consumption during recovery in the post-anesthesia care unit (PACU). Mean PACU opioid consumption in oral morphine equivalents (mEq) in the study group was 37.0 [95% CI: 28.8-45.3] compared to 40.1 [95% CI: 31.8-48.4] in the control group (P=0.29). With the numbers available, intraoperative intra-articular morphine and clonidine injection showed no statistically significant difference in PACU postoperative opioid consumption compared to normal saline control after hip arthroscopy.

Keywords: Intra-articular injection; Morphine; Clonidine; Hip arthroscopy; Opioid consumption.

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Clinical Trial Registration: clinicaltrials.gov NCT02530151; approved 8/18/2015

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Introduction

The application of hip arthroscopy as a treatment for various hip conditions is becoming increasingly popular(1, 2). With most of these cases being performed in the outpatient setting, pain control remains a high priority for both the patient and the care team. Many patients with pain after hip arthroscopy require significant doses of opioid analgesic in the post-anesthesia care unit (PACU), which is effective in short-term pain relief but increases systemic opioid complications and length of stay (3). Furthermore, many patients are sent home with opioids for further pain relief in the days to weeks following surgery. As a result, reducing postoperative pain and shortening recovery times, while limiting systemic exposure to opioids, remains a challenge from both a patient satisfaction and case management perspective.

A variety of preoperative and intraoperative techniques, such as femoral nerve block and intra-articular (IA) bupivacaine injections, have been proposed to decrease pain and opioid consumption in the postoperative setting. Though these techniques limit the exposure to systemic opioids, femoral nerve blockade increases fall risk and IA local anesthetic injections, including ropivacaine, have been shown to be chondrotoxic, limiting the utility of these techniques (4-7). One study in rats showed that compared to saline-injected knees, healthy knees injected with 0.5% bupivacaine demonstrate up to a 50% decrease in density of chondrocytes in the joint (8). Morphine binds to μ-opioid receptor at both central and peripheral tissues. While perhaps the most notable opioid receptors exist in the brain and gastrointestinal tissues, evidence also supports presence of opioid receptors in the joint space (9-11). Furthermore, the poor lipid solubility of morphine inhibits its distribution across the synovial membrane and out of the joint after IA injection, which decreases systemic exposure (12). It also has the added benefits of circumventing both chondrotoxicity and impaired neuromuscular function. In regards to clonidine, a 2014 systematic review by Sun et al demonstrated an immediate postoperative analgesic effect after knee arthroscopy without any evidence of chondrotoxic side effects (13). Clonidine binds to α2-adrenergic receptors, leading to a decrease in nerve signaling from C and Aδ pain fibers. Multiple studies have demonstrated an analgesic effect of clonidine after knee arthroscopy, and in one study by Joshi et al the combination of clonidine to IA morphine injection has been shown to potentiate the analgesic effects of morphine 5-fold (14, 15). While supporting literature and evidence regarding IA morphine injections for postoperative pain control in knee arthroscopy is quite robust (9, 16, 17), there remains a paucity of data for such techniques in hip arthroscopy. One prior retrospective study demonstrated a nearly 43% decrease in PACU opioid requirement with use of IA morphine and clonidine injection, which highlights the potential for pain reduction and clinical significance of this intervention (18).

The purpose of this study is to determine the efficacy of intra-articular (IA) morphine and clonidine hip injection immediately after hip arthroscopy in reducing opioid consumption in the immediate and extended postoperative period. We hypothesized that patients who received the IA injection of morphine and clonidine would have reduced opioid consumption in the postoperative recovery period.

Materials and Methods

Participants

After approval from our university's institutional review board was obtained, patients undergoing primary hip arthroscopy by a single, fellowship-trained orthopaedic surgeon between December 2015 and December 2016 were considered eligible for enrollment in this prospective, parallel, randomized, triple-blind, controlled trial. This study was registered with www.clinicaltrials.gov (NCT02530151 approved 8/18/2015) where a full trial protocol can be found. No major changes were made to the trial design after commencement of the study. All patients were considered eligible for this study except for pregnant women, patients under 18 years of age, and those

undergoing revision procedures. All data was collected at a single, academic institution in a major US city. Of note, funding for drug supply and drug administration came from an annual educational grant from Smith & Nephew, though their company had no other role in the design, methods, or outcomes of the trial.

On the day of surgery, a member of the research team enrolled patients into the study. Following patient's written consent on the day of surgery, a computer-generated list sequentially randomized patients into either the control or the study group. The list was created by pharmacists who were not involved in patient care. The pharmacists then prepared the IA injection in accordance with the respective group—the control group received 11 mL of 0.9% NaCl solution and the study group received 11 mL of 10 mg morphine and 100 mcg clonidine in 0.9% NaCl solution. After preparation, the solution marked "Investigational Protocol 11 mL IA injection" was delivered to the operating room for IA injection at the conclusion of the case. The surgeon, surgical staff, perioperative nurses, research team, and the patient were blinded to the contents of the injection. A sequential list of the random allocation sequence and respective participants was kept by the investigational pharmacy in a separate location from the operating room pharmacy and was only unblinded at the time of statistical analysis.

A standard preoperative pain treatment protocol was administered for all patients enrolled in the study. This regimen consisted of 400 mg celecoxib and 1000 mg acetaminophen given orally 1 hour prior to the scheduled time of surgery. No patients underwent femoroplasty or T-shaped capsulotomy, as osteoplasty was focused solely on the central compartment for all patients, which is consistent with a recent study demonstrating the efficacy of isolated acetabuloplasty alone in treating combined-type FAI (19). The intraoperative IA injection was administered under visualization through the anterior portal at the conclusion of the arthroscopic procedure but prior to removing the hip from traction to ensure proper placement within the hip joint. All intraoperative and postoperative treatment protocols were identical between both the control and study groups. All patients received postoperative ondansetron and dexamethasone (0.1mg/kg; maximum dose 8mg) per anesthesia protocol for nausea and vomiting in the PACU.

The postoperative pain control protocol included intravenous medication (fentanyl, hydromorphone, meperidine) as needed for breakthrough pain, assessed by the PACU nursing staff as a result of patient reported pain levels. Additionally, oral opioids (hydromorphone, hydrocodone/acetaminophen) were administered for longer lasting relief upon discharge from the outpatient care center. All patients were sent home with a standard multimodal pain control regimen, including Norco (hydrocodone 5mg-acetaminophen 325mg), naproxen 500mg twice daily, and aspirin 325mg twice daily (primarily prescribed for deep vein thrombosis prophylaxis).

A total of 180 patients underwent hip arthroscopy from a single surgeon at our institution between the start of recruitment in December 2015 and the end of recruitment in December 2016.

Between the two groups, baseline characteristics were similar, including age, BMI, duration of surgery, and concomitant procedures (Table 1). All patients in the study underwent hip arthroscopy, labral repair, and acetabuloplasty. Intraoperative opioid requirement between both groups was similar (Table 2).

Outcomes Assessed

Opioid consumption during the immediate postoperative period in the PACU was assessed as the primary outcome, and was measured in oral morphine equivalents (mEq) calculated using the respective conversion factor from http://www.globalrph.com/narcotic.cgi (20). All postoperative pain scores and medication administration were assessed by PACU nurses and recorded in the EMR in actual time for eventual data collection by the research team. Secondary outcomes included: postoperative opioid consumption at 6, 18, 24, 48 hours, and 7 days; patient reported pain scores were assessed via Numeric Pain Rating (NPR) scores in the immediate postoperative period and 6, 18, 24, 48 hours, and 7 days postoperatively; time until ready for discharge from the PACU; Quality of Recovery (QoR) scores were assessed in the preoperative waiting area as well as 24 hours post operation using the QoR-15 questionnaire, a validated questionnaire for surgical recovery (21).

Additional data recorded included duration and type of procedure, intraoperative analgesic consumption, and all patients were sent home with a postoperative diary for recording pain scores, medication usage, 24-hour QoR evaluation, and potential side effects, including postoperative nausea, vomiting, constipation, itching, and dyspnea. Patients were asked to return their diary at their first postoperative follow-up appointment. Upon discharge from the PACU, they were

Table 1 Demographics and procedures.

	Control Group	Study Group	P-value
Age (years)	36 [32, 40]	40 [36, 45]	0.18
Gender			
Male	14 (42)	12 (32)	0.39
Female	19 (58)	25 (68)	
Smoker			
No	30 (91)	35 (95)	0.55
Yes	3 (9)	2 (5)	
BMI (kg/m^2)	26 [24, 27]	26 [25, 27]	0.99
Surgical duration (min)	42 [39, 46]	44 [39, 49]	0.59
Concomitant Procedures			
Iliopsoas lengthening	11 (33)	5 (14)	
IT band windowing/ trochanteric bursectomy	6 (18)	11 (30)	
Loose body removal	0 (0)	1 (3)	
Recovery time (min)	172 [157, 187]	172 [158, 186]	0.49

Data reported as mean [95% Confidence Interval] or as absolute values, N (%)

Table 2 Total Opioid consumption in oral morphine equivalents.

	Control Group	Study Group	P-value
Intraoperative	56.0 [47.6, 64.4]	57.3 [50.6, 63.9]	0.40
Postoperative			
PACU	40.1 [31.8, 48.4]	37.0 [28.8, 45.3	0.29
6 hours	5.3 [3.0, 7.6]	5.5 [3.7, 7.3]	0.44
18 hours	13.8 [8.7, 18.9]	14.5 [10.6, 18.4]	0.41
24 hours	20.0 [12.1, 27.8]	19.5 [13.9, 25.1]	0.46
48 hours	35.6 [18.3, 52.9]	27.7 [19.5, 35.9]	0.26
7 days	73.8 [31.6, 115.9]	50.7 [29.6, 71.7]	0.99

reminded once to complete and return the diary, but no patients were asked to complete their diary if they had not done so at their first postoperative appointment due to concern for recall bias. No changes were made to the collected outcomes after the study commenced.

Statistical Analysis

Sample size calculation was drawn from the results of the only known prior retrospective study assessing IA morphine and clonidine injections in hip arthroscopy, where median PACU opioid consumption was 40 mEq (IQR 28-60) (18). The effect size (0.97) was calculated using the correlative mean and standard deviation data from the aforementioned retrospective cohort. With the assumption that IA morphine and clonidine injection reduces opioid consumption, and considering a 30% reduction to be clinically significant, an a priori power analysis estimated 42 total patients required with an α coefficient of 0.05 and a power of 0.8. An allocation ratio of 1.05 was used to reflect the distribution of the retrospective cohort. Recruiting was extended beyond the a priori analysis to help account for loss to follow-up.

Statistical comparison was performed using the Student's t-test for continuous variables and a chi-square analysis for categorical variables. Significance was defined as an alpha level of <0.05. All P-values for primary and secondary outcomes data were reported using the 1-tailed t-test as our goal was to determine whether patients receiving the morphine and clonidine injection had decreased scores compared to those who did not. All demographic data was analyzed using a 2-tailed t-test.

Results

Mean postoperative opioid consumption in the PACU was 37.0 oral morphine equivalents (95% CI [28.8,45.3]) in the study group compared to 40.1 oral morphine equivalents (95% CI [31.8,48.4]) in the control group (P=0.29, N=70) (Table 2). At 6, 18, and 24 hours, opioid consumption was similar between groups. At 48 hours, mean opioid consumption was 7.9 mEq lower in the study group (P=0.26, N=33). At 7 days, mean opioid consumption was 23.1 mEq lower in the study group (P=0.16, N=33) (Table 2).

Mean NPR score immediately postoperatively was 3 (95% CI [2,4]) in the study group compared to 4 (95% CI [3,5]) in the control group (p=0.19, N=70). One hour postoperatively the mean NPR score was 4 (95% CI [3,5]) in the study group compared to 5 (95% CI [4,5]) in the control group (P=0.08, N=70). With the numbers available, there were no statistically significant NPR pain score differences at any other time points. Mean preoperative QoR-15 score in the control group was 131 (95% CI [125,137]) compared to 123 (95% CI [108,138]) in the study group (P=0.29, N=70). At 24 hours postoperatively, the mean decrease in control group QoR-15 score was 20 (95% CI [10,29]) compared to 22 (95% CI [9,35]) in the study group (P=0.74, N=33).

Both groups had a mean time until ready to PACU discharge of 172 minutes (Table 1). Of note, all patients were discharged home from the PACU of the same-day surgery center. Four patients in the study group compared to zero patients in the control group reported nausea at 48 hours, though neither group reported any vomiting. With the numbers available there were no significant differences in nausea, constipation, dyspnea, or itching at any other timepoints.

Discussion

The results of this triple-blind, randomized controlled trial of 10mg IA morphine and 100mcg clonidine injection versus placebo during hip arthroscopy showed no significant decrease in postoperative opioid consumption in the PACU for the study group.

A modest average decrease in opioid consumption of roughly 3 oral morphine equivalents was noted in the study group in the PACU, which was not statistically or clinically significant. At 2 and 7 days postoperatively, a more pronounced difference of 8mEq and 23mEq, respectively, was observed in favor of the study group. No statistical significance was found, as these comparisons outside of the PACU were underpowered due to relatively low rates of completion of postoperative diaries—33 of 70 patients returned their diary at the first postoperative appointment. We would argue, however, that this finding is important to consider. A difference of 23mEq translates to four to five 5mg hydrocodone tablets or 1.25mg IV hydromorphone, as well as a 30% decrease from the control group. A study by Cunningham et al assessed total opioid pills taken 2 weeks postoperatively for arthroscopic treatment of FAI, showing that patients without a history of prior opioid use took an average of twenty 5mg oxycodone, or 150mEq, by the 2-week mark (22). A 23 mEq decrease, as we observed at the 1-week mark, would represent at least a 15% decrease. Given the concern for opioid prescription overuse and misuse, it is important to consider all modalities which may decrease the need for additional or unnecessary home opioids.

A previous retrospective cohort study of a similar patient population showed a mean decrease of 17mEq opioid consumption in the PACU for the study group following the morphine/clonidine injection (18). This discrepancy with data from this prospective randomized study is likely due to lack of blinding in the retrospective cohort and resulting possibility for bias in opioid administration following surgery. The retrospective study did not collect further data at home in the days following surgery, which is also an important period for pain control and reasonable opioid consumption.

Regarding recovery time, there was no difference in time spent in the PACU between study and control groups, which was not a surprising result given the similar pain scores and the use of standard discharge protocols at a single, university-affiliated outpatient surgical center. A

proposed benefit of improved postoperative pain control is decreased recovery times; however, this study was an effectiveness trial based upon clinical practice, and at a large hospital with standardized institutional criteria for PACU discharge, recovery times may not accurately reflect true patient recovery.

The proposed mechanism for effectiveness of IA morphine is due to the presence of μ-opioid receptors in chondrocytes, which inhibit sensory neuron activity from the joint. Unlike other agents commonly used as pain control modalities, such as local anesthetic or NSAIDs, morphine has been shown to be safe in the joint space (23). Additionally the poor lipid solubility of morphine inhibits its distribution across the synovial membrane and out of the joint space after IA injection (9, 12). By injecting the IA solution through the trochar without violation of the capsule beyond trochar placement, it is believed that the injectate remains primarily in the hip joint. One study by Brandsson et al demonstrated very low circulating serum levels of morphine following IA injection for patients undergoing ACL reconstruction, which demonstrates the localization of the injection and also supports the peripheral effect of opioids in the joint space (10). This also decreases the potential for systemic opioid exposure and related side effects.

Postoperative pain control remains a significant factor in patient recovery, satisfaction, and outcomes in orthopaedic surgery, particularly in regards to hip arthroscopy (24). In a healthcare environment that is increasingly driven by patient reported outcomes and satisfaction scores, pain control is an important component of healthcare delivery. A recent systematic review by Shin et al demonstrated the importance of a multimodal approach to pain control after hip arthroscopy, citing numerous modalities of pain control such as femoral nerve block, IA injection, periacetabular injection, and preoperative celecoxib (24, 25). This systematic review drew a few important conclusions, and the most important was that—given a lack of superiority for one particular form of pain control—a multimodal approach remains the best option for decreasing postoperative pain. The available data from our trial do not show a significant decrease in opioid consumption or pain scores in the PACU after IA morphine and clonidine injections, it does suggest a decreased opioid consumption one week after surgery, thus warranting further analysis. The low risk profile of IA morphine and clonidine injection make it an attractive option to be included in a multimodal regimen as well.

Limitations

The conclusions of this study can only be interpreted within the confines of its limitations. First this study was subject to a problem that all postoperative pain management studies endure, which is the heterogeneity of the pain response. This makes it difficult to collect unbiased and consistent markers of pain control. We tried to compensate for this problem by recording multiple outcomes. Regarding quality of recovery measurements, the 24-hour mark may have been too soon to assess quality of recovery, as many of the questions ask about activities of daily living that may not have been tested yet. The decision to test at 24 hours was made based upon prior studies of postoperative pain control in hip arthroscopy, but our data indicate that testing at 48 hours or 7 days may yield more clinically applicable data (26). Additionally, patients were not screened ahead of time for chronic opioid use, which increases generalizability of the study but may mask potential effects of the intervention and postoperative opioid requirements. Unlike the retrospective analysis, this study extended timepoints beyond the PACU period. However, there was a low yield on return of patient diaries, as most patients simply forgot to fill out or return their diary despite multiple reminders, which may have affected the results. However, each group demonstrated similar rates of diary completion, making it unlikely that one group was affected disproportionately from the other. Lastly, this analysis was a single center trial, and no data exist for prospective or retrospective studies outside this practice.

Conclusion

Data during the immediate postoperative period does not show a significant benefit to the IA injection of morphine and clonidine after hip arthroscopy, but a trend toward decreased opioid consumption in the study group was seen at seven days and as early as two days after surgery. Given the potential benefit of these injections in reducing opioid consumption in the week following hip arthroscopy, in combination with the low risk profile of IA morphine and clonidine and the current opioid epidemic, IA morphine and clonidine injections play an important role in multimodal anesthesia. Further pain management research including analyzing opioid consumption in the weeks following hip arthroscopy is warranted.

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Patient Satisfaction in Outpatient Total Shoulder Arthroplasty

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Abstract

There has been a recent trend toward performing joint replacement in the outpatient setting. The objective of this study was to retrospectively evaluate and report on our initial 29 patients that underwent outpatient total shoulder arthroplasty (TSA). There were no re-admissions or emergency room visits for any patients during the 90-day post-operative period. 86% of patients said their pain was very well controlled post-op and 14% said their pain was moderately controlled. 89.6% of patients said they would prefer to go home the same day if they were to undergo TSA again. 96.5% of patients were satisfied with their TSA and outcome at a minimum of 6 months post-op. This initial report corroborates with previous studies that show outpatient TSA is safe. We also showed a high degree of patient satisfaction.

Keywords: Total Shoulder Arthroplasty; Outpatient.

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Email:

Background

Joint replacement has historically been a procedure requiring an inpatient stay post-operatively. Recent advances have allowed for outpatient hip and knee replacement with good outcomes (1,2). Benefits of outpatient joint replacement can include decreased costs and decreased risk of hospital acquired infection while maintaining similar outcomes and patient satisfaction. Several studies have shown similarly good outcomes for outpatient total hip and knee arthroplasty when compared to inpatient cohorts (3,4). Brolin and associates were the first to show that outpatient total shoulder arthroplasty (TSA) was a safe alternative to the procedure performed in an in-patient setting (5). They also concluded that further investigation is needed to evaluate the longer-term outcomes and cost-effectiveness of outpatient TSA. Dunn and associates looked at TSA in the outpatient vs in-patient setting and found that careful selection of patients that meet specific criteria is needed for decreased hospital stay and increased likelihood of a successful outcome (6). In our institution, outpatient hip and knee arthroplasty has been performed for over five years. We followed the program set in place and have been performing outpatient TSA for the last 3 years. Our purpose in this study was to evaluate the short-term outcomes and patient satisfaction of our first 29 patients. We hypothesized that we would have outcomes similar to those seen in the in-patient setting with high levels of patient satisfaction.

Methods

We retrospectively reviewed the charts of 29 patients who underwent outpatient shoulder arthroplasty from December 2014 to January 2018. Institutional Review Board approval was obtained for the review. After review of the charts, all patients were contacted by one of the authors and underwent a brief 5-10 minute survey about their experience.

Patient Selection:

All patients were selected by the senior surgeons (SN, JL) based on health status and desire to go home after surgery and consented to outpatient TSA. All patients were given our standard total shoulder book detailing the procedure, pre-operative preparation, day of surgery details, and post-operative care protocol. All patients met with the surgeon or his physician assistant prior to surgery to answer any final questions. Patients underwent standard and routine medical evaluation by their medical doctors and were cleared for the proposed procedure. Patients were also evaluated by the anesthesia team at the facility and cleared as well. The average American Society of Anesthesia (ASA) classification was 1.93 ± .53 with all but three patients being classified as 1 or 2. Three patients had an ASA classification of 3. The mean BMI of the group was 28.0± 6(range 19.6 – 47.5). The mean age of the group was 57.9± 7.4 (range 38-68) years. There was a total of 19 males and 10 females. (Table 1)

Table 1 Demographics of the outpatient total shoulder arthroplasty subjects.

Variable	
Number of patients	29
Number of shoulders	31
Percentage of males	66%
Average age (years)	57.9 ± 7.4
Age range (years)	38-68
Average BMI	28.0 ± 6
Average ASA class	1.93 ±.53

Surgical Procedure

All patients underwent TSA in the standard beach chair position under general anaesthesia in the ambulatory surgery setting. 25 patients received a single shot interscalene block and 4 patients received the block with an additional in-dwelling interscalene catheter that was removed 3 days post-operatively by the patient's family. All patients had the option to rent an ice machine to help with post-operative pain. The patients were evaluated and managed in the recovery room and were discharged to home directly from the recovery room based upon standard discharge criteria. Length of time in the recovery room was noted. All patients were contacted the next day by the nursing team at the ambulatory surgery centre and any issues were noted and

passed on to the surgeon's office. All patients had narcotic medication available at home and were seen in the office by the surgeon at 10-14 days for initial follow-up. The patients were then started on physical therapy and maintained in the sling for a period of 6 weeks post-operatively. The patients were seen again at 6 weeks and 4 months post-operatively. Some patients were seen again at 6 months and one-year post-op, while others were seen again only at the one year mark.

Patient outcomes and satisfaction:

All patients followed a standard post-op protocol utilizing a sling with protected external rotation for 6 weeks post-operatively. Pain scores, range of motion, and strength were evaluated at each office visit along with post-operative radiographs of the operated shoulder. Progress with physical therapy was also evaluated and progression to a home program was done when appropriate. At the 6-week or 4-month visit the patients were asked by the surgeon if they could be contacted via telephone by an office staff member for a brief 5-10 minute survey regarding their outpatient TSA experience. All patients consented to this interview. The patients were then directly contacted via telephone by one of the authors for an interview regarding their satisfaction with the outpatient protocol. The survey consisted of 8 questions aimed at assessing initial outcomes and satisfaction. All patients were asked about their current level of satisfaction as well as their level of pain control after the surgery. Patients were also asked if they had to contact the on-call physician or visit the Emergency Department after the procedure. Finally, we asked if they would undergo outpatient TSA again or if they would prefer staying in the hospital overnight.

Patients that were 2 years out from surgery were contacted in July 2018 via telephone to answer follow-up survey questions. They were assessed using the SANE scoring system for shoulder function and asked about their current level of pain. They were also asked if they were still satisfied with their shoulder replacement.

Results

All of the 29 patients, who underwent outpatient TSA, responded to our initial survey. The average shoulder pain level was 0.68 ± 1.1 (0-10) and ranged from 0 to 3.5 at a minimum of 4 months post-op. We also assessed the function of the shoulder replacement utilizing the SANE score. The average SANE score was 91.5 ± 9.7 % (0-100%) and the range was from 68-100%. One patient was excluded from this analysis as she suffered a fall resulting in a large rotator cuff tear 2 months post-operatively. She was doing well at the 6-week mark and was happy with her outpatient experience at that visit. She ultimately needed conversion to a reverse replacement.

Out of the 29 cases examined, 26 patients (89.6%) preferred same-day discharge and 3 patients (10.4%) preferred the option of one night inpatient stay. Average time to discharge was 6 hours and 10 minutes. We also evaluated the patients' overall satisfaction in terms of pain control from the surgery. All of the patients found the nerve block to be beneficial and would have the nerve block again for the same procedure. Sixteen patients (55%) used an ice machine and found it to be helpful in controlling swelling and pain. However, the patients who chose not to rent out the ice machine found effective alternative methods of applying cryogenic therapy such as using regular store-bought ice packs. 25 patients (86%) reported that their pain was very well controlled while the other 4 patients (14%) stated that their pain was only moderately controlled. 2 patients (6.8%) experienced the need to contact an on-call orthopaedic surgeon on the night following the surgery. The reasons for the calls involved questions regarding the prescribed medications for pain management. One patient needed additional instructions about how to take the pain medications and the other patient developed an adverse reaction to the pain medication that was prescribed and requested an alternative medication. There were no reported cases of Emergency Department visits within the first week of surgery for pain control or any other issues. There were no re-admissions within the first 90 days from surgery in the group. 28 patients (96.5%) said they were satisfied with their shoulder replacement. The 1 patient that was not satisfied was the patient with the fall resulting in a torn rotator cuff. A revision to reverse replacement was performed at 4 months-postoperatively.

Patients that were at least two years out from their surgery were contacted via telephone in July 2018 to answer survey questions. Out of 24 patients contacted, 15 patients (16 shoulders) answered our 2-year follow-up questions. 100% said they were still satisfied with their shoulder replacement and happy with the outcome of their shoulder. The average shoulder pain level was .35± .63 (range 0-2). The average SANE score to measure shoulder function was 93.1± 6.6 (range 85 – 100).

Discussion

There has been a definite trend towards shorter length of stay in joint replacement surgery over the past decade, which has led to the development of fast-track protocols that allow patients to be discharged quickly after their joint replacement (7,8). Outpatient joint replacement is attractive because of a shorter length of stay and reductions in hospital costs, which can be as significant as appx. $6,000 per patient for THA (9). As this becomes more accepted, surgeons must prove that safety, efficacy, outcomes, and satisfaction with outpatient joint replacement surgery is equal to or better than inpatient joint replacement surgery. In a selection of 27 patients that underwent THA, the outcome of outpatient THA proved to be successful in 24 patients who did not have any complications after same day of discharge. 1Gromov and associates conducted a study with 557 unselected patients and showed that outpatient THA and TKA was viable in only 15% of the patients (10). Therefore, careful selection of patients must be done to ensure re-hospitalization does not occur.

A paucity of data exists in the literature regarding outpatient TSA. Brolin and associates reviewed a case matched series of 30 patients undergoing outpatient TSA compared to an age and co-morbidity matched series undergoing traditional in-patient TSA and found the two cohorts to be equal with regards to early outcomes including complications, hospital re-admissions, and re-operations (5). They recommended further investigation to evaluate the longer-term outcomes and cost effectiveness of outpatient TSA. Cancienne and associates reviewed data from 706 patients who underwent outpatient TSA and they found no increases in complication or re-admissions in ambulatory TSA compared to inpatient TSA (11). They also suggested that outpatient TSA represents a significant cost savings, appx. $3,500 per patient, compared to in-patient TSA. Furthermore, Dunn and associates looked at length of stay after elective TSA and concluded that some criteria that predispose a patient to a longer stay are renal insufficiency, increased age, ASA class ≥ 3, and being female. 6This reiterates the importance of screening and selecting patients that meet specific criteria before attempting outpatient TSA. In addition, motivation level and social support should also be considered.

The main reason TSA is routinely done in an in-patient setting is to manage pain post-operatively. Ilfed and associates conducted a study looking at the potential of outpatient TSA with the use of a nerve block and continuous infusion pump for analgesia (12). This method resulted in pain that was well controlled post operatively, and a significant number of patients were discharged to go home on the same day. This is a similar method that our institution uses for analgesia during outpatient joint replacement.

Our study represents a small series with 2-year outcomes, but also attempts to evaluate patient satisfaction. We found outpatient TSA to be safe with a low complication rate and promising early outcomes. We also found patient satisfaction with the entire episode of care to be extremely positive with a high percentage of patients stating they would undergo outpatient TSA again. There were three patients who responded that they would prefer inpatient TSA in the future. One patient had a history of generally not responding well to anaesthesia. Another developed adverse reactions to narcotics post-operatively as the patient had no prior narcotic history. The third patient felt she needed further clarification of instructions with taking pain medications. She did admit that she called the on-call doctor and her questions were answered to her satisfaction. All patients were satisfied with their shoulder replacement at a minimum of 6 months out except for 1. The 1 patient that was not satisfied with the outpatient TSA had a fall, which resulted in a rotator cuff tear 2 months after surgery. This required us to convert the anatomic shoulder replacement to a reverse. We feel that her dissatisfaction with her initial shoulder replacement was not due to it being done outpatient, but due to the fact she had an accident post-op. Also, the same patient did state initially that if she were to undergo TSA again she would do it as an outpatient procedure.

There are several factors that we feel were vital to the success of our series and will be helpful for surgeons considering outpatient TSA. First, there was a selection bias as the patients represented a healthy and motivated cohort of patients willing to be the first to undergo the procedure in an outpatient setting. During our collection period, there was no data in the literature on the safety and efficacy of outpatient TSA. As such, the senior authors were careful in selecting patients that felt to be at low risk of complication and highly motivated with a good social support system in place. We feel this was vital in our initial success and positive results. This represents an inherent limitation of this study.

Secondly, the senior surgeons (SN, JL) perform a high volume of shoulder replacements with both performing over 100 per year. Both have developed a shoulder replacement pathway that includes a standard and detailed pre-operative education program as well as standard post-operative pathway that we feel is critical to the success and satisfaction of patients. Utilizing such a program on a routine basis, in our opinion, was vital in the transition to outpatient TSA. Many surgeons may rely on the hospital to perform post-operative education and set up key post-operative elements such as PT and home health. In our institution, this is all covered before surgery. This is also reflected in that only two patients felt the need to call the on-call doctor with questions.

Finally, aggressive management of pain peri-operatively is routine for all joint replacements in our institution. Adapting this to our shoulder patients allowed us to shorten our length-of-stay to the point where we felt comfortable sending patients home directly from the recovery room. Ultimately, good pain management has allowed us to transition to the ambulatory surgery setting. This was corroborated by the high percentage of patients who felt their pain was very well controlled. There were no patients who felt their pain was not adequately controlled.

Another limitation is that our study is retrospective in nature. As such, the group was not randomized. The study is also limited by the short-term follow-up of the shoulder replacements. Similar to the prior study by Brolin and associates, we recommend longer term studies to assure that outpatient TSA is truly equal to inpatient TSA. Basques and associates analyzed the Medicare dataset from 2005-2012 to compare complications and re-admission rates between the outpatient TSA vs in-patient TSA (13). They found lower complication rates and lower re-admission rates for the outpatient cohort. Outpatient TSA represented 2.8% of the entire population studied. This analysis shows promise for outpatient TSA. However, this is a retrospective database study and has inherent limitations.

We feel a true randomized study is needed with long-term follow-up. Despite these limitations, our purpose was to evaluate our initial group of patients and evaluate the success and satisfaction of this group. We feel this goal was achieved. Our study is the first to document patient satisfaction with regards to outpatient TSA. Our survey revealed a high percentage of patients who would undergo TSA as an outpatient again. As a result, we feel that outpatient TSA has significant promise to become standard for a large group of patients. At present, there are no guidelines for the selection of candidates for outpatient TSA. Our current group represented an ideal cohort with healthy and motivated patients who had good pre-operative counselling and social support. We recommend that surgeons, considering transition to outpatient TSA, develop strong protocols for peri-operative management of pain and patient expectations. If patients have no history of narcotic usage, we recommend giving patients their pain medication prescriptions pre-operatively and asking them to try a pill to assure no adverse reaction is noted. We recommend a strong pre-operative program to educate patients regarding limitations, wound care, and expectations. We also recommend implementing these protocols and educational pathways in the hospital setting prior to transitioning to the ambulatory surgical setting. Finally, we recommend selecting patients initially that are healthy, have no history of problems with anaesthesia, and are motivated to undergo outpatient TSA.

In conclusion, our study shows excellent 2-year patient satisfaction with outpatient shoulder replacement. Our initial outcomes and complication rates are similar to those noted with inpatient TSA and patient satisfaction was extremely high. Proper selection of patients as well as a streamlined pathway with proper peri-operative education and pain management are keys to success. Our study corroborates other studies that show promise for outpatient TSA. Further investigation should focus on evaluating long-term outcomes and cost effectiveness in a randomized multi-center trial.

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Pain in Ambulatory Surgery: 4 Year Experience of an Ambulatory Surgery Unit in a Tertiary Hospital

N.M. Rodrigues, P. Ribeiro, F. Jesus, M. Caldeira

Abstract

There has been a recent trend toward performing joint replacement in the outpatient setting. The objective of this study was to retrospectively evaluate and report on our initial 29 patients that underwent outpatient total shoulder arthroplasty (TSA). There were no re-admissions or emergency room visits for any patients during the 90-day post-operative period. 86% of patients said their pain was very well controlled post-op and 14% said their pain was moderately controlled. 89.6% of patients said they would prefer to go home the same day if they were to undergo TSA again. 96.5% of patients were satisfied with their TSA and outcome at a minimum of 6 months post-op. This initial report corroborates with previous studies that show outpatient TSA is safe. We also showed a high degree of patient satisfaction.

Keywords: Postoperative pain, Ambulatory Surgery.

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Introduction

At present, the number and complexity of surgical procedures performed in ambulatory setting are increasing. Ambulatory surgery now accounts for up to 70% of all elective surgical procedures in some countries (1). Moreover ambulatory surgery has gained wide patient acceptance and its cost effectiveness is already proven (2). For these reasons the postoperative pain after ambulatory surgery is getting more and more attention (3,4).

Postoperative pain therapy in ambulatory setting is even more challenging, as it requires effective analgesic techniques with minimal secondary side, which has to be managed at patient's home by themselves. The method of choice is widely variable between Ambulatory Surgery Units (ASU). The majority of ASU use multimodal analgesic approach combining, acetaminophen, dipyrone, nonsteroidal anti-inflammatory drugs, weak opioids, and local or regional anesthesia (5).

Contrary to the common belief that postoperative pain in ambulatory setting is a rare symptom, evidence shows that pain after ambulatory surgery has a high incidence (6).

To provide adequate pain treatment to our population, more information is needed regarding postoperative pain in our ASU. Accordingly, the specific goals are determine the incidence of pain in the first 48hours in our ASU, and the anesthesia technique and surgical specialties that seems to be associated with postoperative pain.

Methods

We analyzed, retrospectively, the clinical data of patient submitted to surgery in our ASU of the Ocidental Lisbon Hospital Center from 1st January 2012 to 31st December 2015.

After appointment with their surgeon, all patients had a consultation with an anesthesiologist who assesses clinical and social conditions for performing the procedure in an ambulatory setting. Then they met the nurse team to the pre-operative counseling. 48 hours before the surgery, a telephone call was made by the nurses to confirm the maintenance of the clinical and social conditions and reinforce the pre-operative teaching. On the day of surgery, one of the anesthesiologist's responsibilities was to evaluate the discharge conditions for home and to instruct the postoperative procedures and analgesia. Patients were discharged from the post anaesthesia care unit to the ASU when their Aldrete scores are 9 or more. The analgesic regimens were in accordance with the recommendations for the treatment of acute postoperative pain in ambulatory surgery, of the Portuguese Ambulatory Surgery Association (5).

All patients who answered the nurse telephone postoperative questionnaire at 24h and 48h were included. Data were registered in a computer database (Access®). Patient demographic information the American Society of Anesthesiology physical status (ASA) and the referral given to situations in which the pain did not alleviate with the prescribed therapy were registered. The number of surgeries performed by surgical specialties and their anesthetic technique were also assessed.

The main outcomes were the presence of postoperative pain at 24h or 48h and the prevalence of pain that does not relieve with prescribed analgesia (uncontrolled pain).

The descriptive statistical analysis was done using SPSS software ® (version 24 IBM corporation), by an investigator without intervention in the surgical procedure or anesthesia. Categorical variables are expressed in absolute number and percentage, and continuous variables are expressed as mean ± standard deviation. Chi-Square test was used to compare categorical variables and a p value of less than 0.05 was considered statistically significant.

Results

We collected data from 6304 patients that were managed in our ASU. The gender distribution was 3530 (56%) female and 2774 (44%) male. The mean age of the patients was 42 years (SD +- 22,0). The distribution according to the ASA was as follows: ASA I - 1650 (26,2%), ASA II -3823 (60,6%), ASA III - 805 (12,8%), ASA IV – 26 (0,4%).

Plastic surgery was the specialty with the highest number of surgeries performed (n=1366) followed by Ear Nose & Throat and Urology

(Table 1). According to the anesthesia technique, general anesthesia has been the most chosen (n= 4423). Regional anesthesia techniques represent more than 15% of all cases with a preponderance of spinal block technique (n= 506) (Table 1).

The follow-up questionnaire was answered by 6008 patients (response ratio of 95.3 %) of which 29.1% (n=1750) reported postoperative pain. Nevertheless the majority of these patients (93%) reported pain relieved with the prescribed therapy.

Uncontrolled pain was reported by 130 patients, which represent 2.2% of all patients (130/6008). The patients who were submitted to Neurosurgery and Orthopedic procedures were those who more frequently mentioned pain that was not relieved with prescribed analgesia: 3.9% (24/618) and 3.7% (24/646), respectively (Table 2). Among anesthesia techniques, regional anesthesia was the one with highest rates uncontrolled pain 3.4% (35/1020). Peripheral block was the technique who perform worse, 3.8% (13/317) (Table 2).

The majority of patients who reported uncontrolled pain required adjustments in the analgesic regimen (50%, N=65), whereas in approximately a quarter of the patients, hospital referral was deemed necessary (21.5% N=28) and in another quarter, enhancement of the clinical advice (23.9%, N=31) (Table 3).

Discussion

Although this study is based in one centre only, some results are similar with other centres and countries (2,4,6,7). The results are based on a telephone questionnaire-survey, with a response ratio of 95.3 % which is slightly higher than other studies (2–4).

Another Portuguese study, fulfilled also in a Tertiary Care Hospital (7) had more General Surgery, Vascular Surgery and Orthopedics' procedures in opposition of Plastic Surgery, ENT and Urology surgery performed in our ASU. However anesthetic techniques were very similar, General Anesthesia 70.6% vs. 70.2%, sedation 18.3% vs. 11.8% and Loco-regional anesthesia 11.2% vs. 16.2%.

Table 1 Patients' distribution according to Surgical Specialties and Anesthesia technique.

Specialties	N (%)
Plastic Surgery	1366 (21.7%)
Ear Nose & Throat	861 (13.6%)
Urology	840 (13.3%)
Gynaecology	789 (12.5%)
Orthopedics	646 (10.2%)
Neurosurgery	618 (9.8%)
General Surgery	604 (9.6%)
Stomatology	335 (5.3%)
Vascular Surgery	222 (3.5%)
Gastroenterology	16 (0.0%)
Pneumology	7 (0.0%)
TOTAL	**6304 (100%)**

Anaesthesia Technique	N (%)
General Anesthesia	4423 (70.2%)
Regional Anesthesia	1020 (16.2%)
Spinal Block	506 (8.0%)
Peripheral Block	317 (5.0%)
Local	195 (3.1%)
Endovenous Block	2 (0.0%)
Sedation	747 (11.8%)
Combined Anesthesia	56 (0.9%)
No register	58 (0.9%)
TOTAL	**6304 (100%)**

Table 2 Uncontrolled pain according to Surgical Specialties and Anesthesia technique.

Specialties	N	(%)	P_value
Neurosurgery	24	3.9%	
Orthopaedic	24	3.7%	
General Surgery	16	2.7%	
Plastic Surgery	24	1.8%	
Stomatology	6	1.8%	<0.001
Ear Nose & Throat	14	1.6%	
Urology	12	1.4%	
Gynaecology	9	1.1%	
Vascular Surgery	1	0.5%	
Total	**130**		

Anaesthesia Technique	N	(%)	P_value
General Anaesthesia	79	1.8%	
Regional Anaesthesia	35	3.4%	
Peripheral Block	13	3.8%	
Spinal Block	18	3.4%	
Local	4	2.1%	0.004
Sedation	12	2.5%	
Combined Anaesthesia	1	1.8%	
No register	3	5.2%	
Total	130		

Table 3 Patients' referral who reported pain unrelieved with prescribed analgesia.

	N	%
Enhance the clinical advice	31	23.9%
Adjustments in the analgesic regimen	65	50.0%
Hospital referral	28	21.5%
No register	6	4.6%

On the other hand, Gramke and colleagues report more general surgery (30%) and orthopedics (26%), procedures with general anesthesia being the technique chosen in 62% of the cases and the loco-regional 38%. (4)

In the first 48 postoperative hours, 29.1% of our patients reported pain, which is similar to McGrath and colleagues (2) but clearly lower than the data presented in other studies, that reports nearly 60% (8,9).

Although our questionnaire did not quantify the pain, for comparison purposes, we assumed that pain that is not controlled with analgesic prescription could be considered severe. The incidence of pain that does not relieve with analgesic prescription (2.2%) is also lower when compared with other studies, that report incidence of severe pain between 5.3% (9)and 20% (8).

These differences in pain incidence may be due not only to the different pain assessment methodologies (yes/no answer in our study vs. assessment scales in other studies) but also to the evolution in pain knowledge and treatment in last years, using combinations of medications with different mechanisms of action in the context of multimodal analgesia, and to the fact that in our ASU there were fewer surgical procedures associated with severe pain (e.g. General surgery, Orthopedic surgery).

As our postoperative questionnaire does not reflect the patients who did not adhere to the analgesia, our results can even be overestimated.

As in our ASU, McGrath and colleagues found that Neurosurgery, General Surgery and Orthopedic Surgery had higher incidence in severe pain (2). Also Gramke and colleagues found that operations of nose and pharynx, abdominal operations, plastic surgery of the breasts, and orthopedic operations of the extremities were the most painful procedures during the first 48 hours (4).

Local and regional anesthesia seems to increase uncontrolled postoperative pain, in our study population. Matilla and colleagues found that general anesthesia supplemented with local anesthesia increase the risk of postoperative pain in either adults or children. (6) Probably the clinical staff overestimates the analgesic effectiveness of local and regional technique and underestimates the importance of counseling on the therapeutic compliance or misjudges the analgesic requirements at home.

Our hospital referral rate due to pain, 0.46% (28/6008), is similar to other hospitals that report rates of 0.26% (2) to 1.5% (6). The low hospital referral rate is low, probably because there is 24 hour telephone support, where anesthesiologists are available to advise and adjust analgesic medication.

Fear for side effects of analgesic medication seems to be a relevant factor affecting patient compliance for postoperative analgesics (4), as Apfelbaum and colleagues revealed that 94% of patients thought that some analgesics prescribed after surgery caused adverse effects (10). Thus, clarifying the patients is cornerstone for optimal pain management after ambulatory surgery.

Selection of analgesic schemes may vary between institutions and countries. However, many of the observations related to pain, namely the surgical specialties, anesthesia techniques, and incidence of pain are consistent with results obtained in outpatient populations in Canada and Netherlands (2,4), suggesting that our results are also relevant to other institutions.

This study allowed us to better understand one of the most important and challenging indicators of morbidity in outpatient surgery: the postoperative pain. We have identified the specialties and anesthetic techniques in which uncontrolled pain is more frequent, which will allow an optimization of the analgesic regimens. Further investigation and development of surgery-specific protocols for management of pain at home will probably improve the quality of recovery after ambulatory surgery.

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Preoperative Anxiety and Volume and Acidity of Gastric Fluid in Paediatric Patients undergoing Ambulatory Surgery

Y. Doi, R. Unita, Y. Hamasaki

Abstract

Aims: To examine the relationship between preoperative anxiety, age, gastric fluid volume (GFVw) and pH among paediatric outpatients undergoing ambulatory surgery.

Methods: An observational study was conducted on patients aged 1-12 years. Preoperative anxiety was evaluated by modified Yale Preoperative Anxiety Scale on admission (mYPAS-ad) and on entry to operating rooms (mYPAS-or). Gastric content was aspirated under general anaesthesia.

Results: Complete data was collected from 119 patients. Mean mYPAS-ad was 36.36, mean mYPAS-or was higher, 48.35. Mean GFVw (ml/kg) was 0.404, pH was 1.55. Patients with higher mYPAS-or had significantly larger GFVw. mYPAS-ad and GFVw were not related. Older children had significantly larger GFVw and lower pH.

Conclusions: Paediatric patients with higher mYPAS-or had larger GFVw in this study.

Keywords: Anxiety, Gastric Fluid, pH, Paediatric, Outpatient, Ambulatory Surgery

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Introduction

Aspiration pneumonia is a serious complication of general anaesthesia. To reduce this risk, guidelines on two-hour clear fluid fasting were established and later updated by the American Society of Anesthesiology in 2017 (1). These guidelines are used as standard in Japan. There are several reports on preoperative anxiety and gastric contents in adult patients (2,3) and in paediatric inpatient settings (4). Relationships between preoperative anxiety and volume and pH of gastric fluid in paediatric outpatients undergoing surgery, however, have not been widely examined. Ambulatory surgery is especially beneficial for paediatric patients in reduction of distress and anxiety because they can be in a familiar environment until just before surgery. We studied the relationship between preoperative anxiety and gastric fluid volume and studied anxiety and pH in paediatric outpatients undergoing general anaesthesia by supraglottic airway device. We hypothesized that any distress from longer waiting time in hospital may affect patient anxiety, gastric fluid and pH.

Methods

This was a prospective, monocentric, observational study conducted in a private hospital (No. 2017-15). As there is no intervention in our study protocol differing from our daily practice, the Takatsuki General Hospital Ethics Committee concluded that there was no need to obtain written consent. Oral informed consent was obtained from patient's parents.

We enrolled paediatric patients aged between one and twelve years, with ASA physical status 1 or 2, scheduled for ambulatory minor surgeries using supraglottic airway device between August 2017 and September 2018. We excluded patients with past history of any kind of surgery within six months, multiple surgeries, gastrointestinal surgery or mental disorder.

Preoperative instruction

All patients could eat until the night before administration. Clear fluid oral intake was without limit between waking time and 07:30 for morning cases, or 11:00 for afternoon cases. Formula milk or breast milk was allowed to be taken until 03:30/ 05:30 for morning cases, or 07:00/ 09:00 for afternoon cases, respectively. In our institution the first morning ambulatory surgery starts at 09:30, the first in the afternoon begins at 13:00.

Anxiety evaluation

Child anxiety was measured by attending anesthesiologists at two time points, using the Modified Yale Preoperative Anxiety Scale (mYPAS) which was developed in 1995 (5) and modified in 1997 (6). Immediately after patient's arrival in hospital around 08:30, an attending anesthesiologist interviewed and assessed their condition in a holding area, and anxiety was measured (mYPAS-ad). After vital signs were taken by a nurse, patients were escorted to a general ward and waited there for surgery with their parents. Upon entry to the operating rooms (OR), anxiety was measured again (mYPAS-or). During patient check-in by OR nurses, the patient's favorite DVDs were played in the OR holding area. The same anesthesiologist took each mYPAS score. Premedication is not usually administered for ambulatory patients in our institution.

Anaesthesia method

After inhalational induction of anaesthesia, a peripheral intravenous cannula was inserted. Airway was secured by laryngeal mask airway (LMA) ProSeal (Teleflex Medical, NC. USA), according to patient's age and weight. A multi-orificed gastric sump tube (Argyle, St. Louis, MO) was inserted without lubricant; 8 Fr for LMA ProSeal sizes 1.5 and 2 and 10 Fr or 12 Fr for LMA ProSeal sizes 2.5 and 3. With the patient in supine position, the gastric tube position was confirmed by stomach auscultation. Gastric content was gently aspirated by syringe in a right lateral decubitus position and in a supine position while gently massaging the hypogastric area. In each position, the gastric tube was moved back and forth several times. Collected gastric fluid was measured by syringe and acidity was measured by colorimetric paper (7) (No. 1-1254-03, AS ONE, Osaka, Japan) by five people independently. Patient gastric pH was defined as mean of the five values.

Primary outcome is any relationship between patient anxiety and gastric fluid volume divided by body weight (GFVw) and gastric pH. Secondary outcome is any relationship between waiting time in hospital and GFVw and gastric pH.

Statistical analysis

Background factors are summarized in Table 1 (near here). Outcomes were GFVw (Table 2)and pH (Table 3), influential factors were age, mYPAS-ad, mYPAS-or and waiting time. Multiple linear regression analysis with backward stepwise algorithm was used to calculate a predictive model. A probability of < 0.05 was considered to be significant. Spearmen rank correlation was performed between waiting time and change in anxiety level. All statistical calculations were made using EZR version 1.36 software package [8] (Jichi Medical University, Saitama, Japan).

Table 1 Patient characteristics and results. Data are presented as mean (standard deviation, S.D.) [range].

Patients No.	119 (Male 71/ Female 48)
Age (yr)	4.54 (2.92) [1.0-12.75]
Height (cm)	100.7 (19.9) [70.4-155]
Weight (kg)	16.7 (7.0) [8.5-44]
mYPAS-ad	36.36 (15.43) [23.33-100.0]
mYPAS-or	48.35 (20.03) [23.33-100.0]
GFVw (ml/kg)	0.404 (0.337) [0.0158-1.816]
pH	1.55 (0.48) [0.70-3.60]

mYPAS-ad: modified Yale Preoperative Anxiety Score on admission.
mYPAS-or: modified Yale Preoperative Anxiety Score on entry to operating rooms.
GFVw: gastric fluid volume divided by body weight.
mYPAS consists of five elements (activity, vocalization, emotional expressivity, state of arousal and use of parents), ranges between 23.33 and 100, with higher score indicating higher anxiety.

Results

During this period, 131 patients underwent ambulatory surgery. Complete data were collected from 119 patients, and 12 patients were excluded because of technical errors in fluid collection, lack of mYPAS evaluation because the patients were asleep during interview on admission and/or on entry to OR, or due to parental decision. None of the patients took any kind of medication. Patient characteristics and results are shown in Table 1. mYPAS-ad and mYPAS-or were 36.36 (15.43) and 48.35 (20.03) [mean (SD)], respectively. GFVw (ml/kg) was 0.404 (0.337) and pH was 1.55 (0.48) [mean (SD)]. Multiple linear regression analysis revealed that older age and higher score of mYPAS-or were independent risk factors for greater GFVw (coefficient 4.14, 95% confidence interval (C.I.) 2.07-6.22, $p< 0.001$, coefficient 3.96, 95% C.I. 0.94-6.98, $p=0.011$), respectively (Table 2).

There was no correlation between mYPAS-ad and GFVw, and no correlation between waiting time and GFVw. Multiple linear regression analysis showed that older age was an independent risk factor for lower gastric pH value (coefficient -3.96, 95% C.I. -6.89-1.03, $p=0.008$) (Table 3). Gastric acidity was not affected by mYPAS-ad, mYPAS-or or waiting time. According to two multiple linear regression analyses, older children showed significantly greater volume of gastric fluid and lower value of pH. From Spearman's correlation analysis, there was no correlation between waiting time and difference obtained by subtracting mYPAS-or from mYPAS-ad (coefficient -0.139, $p=0.131$) (Fig.1)

Statistically, older children showed lower anxiety level on entry to OR. Patients with high mYPAS-or value had larger GFVw, but high mYPAS-ad value did not mean larger GFVw. This means higher anxiety level on entry to OR, is related to higher gastric fluid volume, not anxiety level on admission. Acidity of gastric fluid was not related to anxiety level on admission or entry to OR. Waiting time did not increase GFVw, did not decrease pH, and did not elevate mYPAS-or.

Table 2 Multiple linear regression analysis for GFVw (independent variables were age, mYPAS-ad, mYPAS-or and waiting time).

	Multivariate analysis		**Stepwise (BIC)**	
	coefficient [95%C.I.]	p-value	coefficient [95%C.I.]	p-value
Age $\times 10^{-2}$ (yr)	4.27 [2.18, 6.37]	< 0.001	4.14 [2.07, 6.22]	< 0.001
mYPAS-ad$\times 10^{-3}$	-0.32 [-4.65, 4.01]	0.884	----------	----------
mYPAS-or$\times 10^{-3}$	3.87 [0.39, 7.36]	0.030	3.96 [0.94, 6.98]	0.011
Waiting time$\times 10^{-3}$ (min)	-0.62 [-1.72, 0.47]	0.263	----------	----------

Older patients had significantly greater GFVw ($p< 0.001$). Patients with higher score of mYPAS-or had significantly greater GFVw ($p=0.011$). However, there were no associations between mYPAS-ad, waiting time and GFVw.

Table 3 Multiple linear regression analysis for pH (independent variables were age, mYPAS-ad, mYPAS-or and waiting time).

	Multivariate analysis		**Stepwise (BIC)**	
	coefficient [95%C.I.]	p-value	coefficient [95%C.I.]	p-value
Age $\times 10^{-2}$ (yr)	-3.82 [-6.94, -0.69]	0.017	-3.96 [-6.89, 1.03]	0.008
mYPAS-ad$\times 10^{-3}$	0.77 [-5.66, 7.21]	0.812	----------	----------
mYPAS-or$\times 10^{-3}$	0.30[-4.88, 5.47]	0.910	----------	----------
Waiting time$\times 10^{-3}$ (min)	-0.07 [-1.71, 1.57]	0.933	----------	----------

Older patients had significantly lower pH of gastric fluid ($p=0.008$).

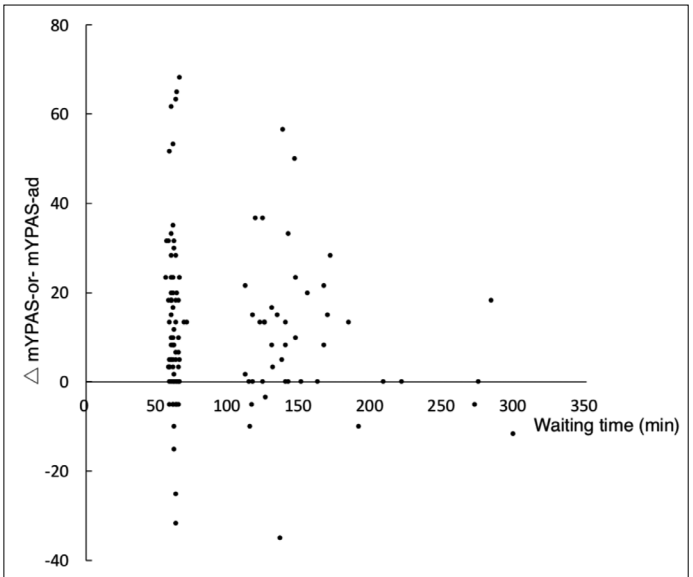

Figure 1 Spearman rank correlation between waiting time in hospital and difference obtained by subtracting mYPAS-or from mYPAS-ad. Waiting time in hospital did not increase patient anxiety (coefficient -0.139, p=0.131).

Older paediatric patients showed significantly higher GFVw and lower pH, and significantly lower anxiety level on entry to OR.

Discussion

Patient anxiety on admission was not associated with changes to GFVw or pH in this study. Contrarily, higher anxiety level on entry to OR was associated with greater GFVw. Distress after arrival in hospital may contribute to increase in GFVw. We hypothesized that distress from longer waiting time in hospital may affect patient anxiety, GFVw and pH, but in this study the hypothesis was incorrect. Factors other than waiting time must therefore be involved in increase in anxiety. At our institution, ambulatory surgeries are scheduled in order of patient age, meaning older patients have to wait longer for surgery in hospital. After receiving age-appropriate preoperative preparation by anesthesiologist upon arrival at hospital, older patients may have less anxiety (9,10). Short waiting time in hospital is not necessarily stressful, and may actually be useful for psychological preparation in school-age children.

Kawana et al (4) reported that a high-anxiety group of inpatients aged between three and six years undergoing surgery showed significantly lower gastric volume than lower anxiety inpatients, but there was no difference in pH. For this reason, they assumed that the cephalic phase of gastric secretion was being suppressed in the high-anxiety group and the increased sympathetic tone disturbed gastric secretion. Regarding gastric volume, our result was completely opposite to their result. There are two major differences between our studies. First, our study is of outpatients, whereas the patients in the previous study patients stayed overnight in hospital before the day of surgery, which might be a source of stress. In their study, the mean GFVw in the low anxiety group was 0.47 (0.26), which is similar to in our study. A second difference between the studies is that our patients were allowed to take clear liquid between waking time and up to two hours before the surgery, whereas oral intake was prohibited after sleep in the previous study, which could also cause hunger, thirst and discomfort. Unnecessary fluid restriction should be avoided since there was no difference in GFVw between the two studies as long as patient anxiety is low.

In this study, we found that two patients presented a full stomach (defined as fluid volume over 1.5 ml/kg) (11). One patient with GFVw 1.51 ml/kg and pH 0.90 was a 12 year-old girl (149.5 cm in height, 37.1 kg in weight), who took 200 ml of isotonic water three hours before induction of anaesthesia, and mYPAS-ad/ mYPAS-or were 36.67/ 31.67 respectively. The other patient, with GFVw 1.81 ml/kg and pH 2.10, was a 5 year-old girl (116.0 cm in height, 20.1 kg in weight), who took 50 ml of isotonic water two hours before induction of anaesthesia and mYPAS-ad / mYPAS-or were 50.00/ 73.33 respectively. There seems to be no common factor for the relatively large residual volume of gastric fluid in these two patients. Recently, it has been recommended to shorten the liquid fasting time to one hour (12) and several clinical studies support this up-to-date clear fluid policy (13,14). Thomas and colleagues (2018) suggest 3 ml/kg as an appropriate volume of clear fluid (15). Despite following conventional ASA clear fluid fasting guidelines and recent consensus statements, two of our patients (1.7%) showed residual gastric fluid, but the percentage is low compared to the 6.2% of patients with a full stomach in a previous report (11). For minor ambulatory surgeries, paediatric patients are usually induced by inhalational anaesthesia and supraglottic device is chosen to secure the airway. If the stomach is inflated by manual mask ventilation, it is safer to aspirate gastric fluid and air because the patient may vomit from distension of the stomach.

There are some limitations to our study, the first is the method of gastric fluid suction. Blind aspiration through multi-orificed catheter in three consecutive patient positions (supine, left lateral and right lateral position) could allow to aspiration up to 96-97% of GFV (16,17). However, we positioned patients in two positions, right lateral decubitus and then supine position. According to ultrasound assessment, most of the gastric content moves from the fundus and body toward the antrum in right decubitus position (18). Underestimation of fluid volume could be minimized by slow and gentle suction if there was sufficient time. Secondly, we used 8 Fr gastric catheter for patients weighing between 8.5 kg and 18.8 kg, 10 Fr for patients weighing between 9.9 kg and 34 kg, and 12 Fr for patients weighing 36 and 37 kg. GFV was low and dead space of a tube was fixed for an 8.5 kg-patient and an 18.8 kg-patient. GFV was corrected by body weight, so dead space may also cause underestimation of collected gastric fluid.

Higher mYPAS-or was associated with greater GFVw. Waiting time in hospital did not affect anxiety level. Other factors could not be clarified from the results of this research, but reduction of patient anxiety should always be considered separate from aspiration risk.

Conclusions

In paediatric outpatients undergoing ambulatory surgery, patients with higher score of mYPAS-or had greater volume of gastric fluid. pH was not affected by either mYPAS-ad or mYPAS-or. Waiting time in hospital did not influence patient anxiety and had no effect on gastric fluid volume or acidity.

Disclosure

The Takatsuki General Hospital Ethics Committee approved the protocol for this study (No. 2017-15). The study was entirely funded by departmental resources. The authors declare that there are no conflicts of interest.

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