Evaluation of an anesthetic pump for postoperative care after shoulder surgery

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In theory, a prolonged, local infusion of anesthetic into a surgical field should reduce postoperative pain. Recently, disposable products have become available to implement this, but the balance between cost and benefit is controversial. This study evaluated such a device in two specific types of arthroscopic surgery of the shoulder: decompression of the subacromial space and repair of a torn labrum in the glenohumeral joint. Placement of the catheter into the glenohumeral joint resulted in problems in removing the device from some cases so that application is not recommended. When the catheter was placed in the subacromial space, the infusion pump was associated with significantly shorter stays in the recovery room, but there was no benefit over placebo with regard to pain, demand for rescue narcotic, or recovery of motion. Furthermore, use of the device presented some inconveniences to the surgical staff and the patient. It was concluded that use of this particular device in these particular applications is not justified. (J Shoulder Elbow Surg 2003;12: 618-21.)

A number of commercial suppliers offer devices that infuse local analgesics subcutaneously through a catheter.[7] One in particular, the PainPump (Stryker Instruments, Kalamazoo, MI) became the focus of this investigation when representatives of the manufacturer offered to sponsor a blinded clinical trial.

A typical application of the PainPump and similar devices is to place the catheter percutaneously at or near a surgical wound after the surgery has been completed but before the patient recovers from the surgical anesthetic. The device is then capable of infusing anesthetic from a reservoir for 1 or more days without patient control.

The costs for these devices vary from a few hundred dollars for simple, passive infusers to a few thousand dollars for programmable instruments. Other costs include training and effort on the part of the surgical team, inconvenience for the patient, risk of infection at the catheter portal, and risk of device failure.

Whether analgesic infusers are effective in reducing overall postsurgical pain and in reducing demand for rescue medications is controversial. Commercial suppliers of these devices offer little in the way of unbiased scientific confirmation. Surgeons use these devices feeling that they have very low risk (principally, infection at the catheter portal) and may provide clinically significant benefit. Patients tend to favor the benefits over the risks but may balk at carrying the reservoir for 1 or more days or trying something that is unfamiliar to them. Administrators resist their use because the price is significant, some insurance carriers may not cover the costs, and there are additional costs associated with training the staff, applying the device, educating the patient, planning for failures, and keeping an inventory.

Thus, there is a need for studies to determine the effectiveness of local analgesic infusion devices used to control postoperative pain. A few reports on disposable, mechanical devices have been published.[1,2,5-8] We tested one such item in a blinded, placebo-controlled study involving surgery of the shoulder.

MATERIALS AND METHODS

The study was approved by our Institutional Review Board. Eligible subjects were those undergoing arthroscopic surgery of the shoulder for decompression of the subacromial space or arthroscopic repair of a superior labrum anterior-to-posterior (SLAP) or Bankart lesion in the glenohumeral joint. Candidates were screened to eliminate those who had had previous surgery on that shoulder, those with complicating medical conditions (such as a history of arthritis), and those who would not be available for follow-up.

In a random process, the surgery staff was instructed to install an analgesic infusion device in the normal fashion or

to install a placebo version of the device in which the spring was not released (and, thus, no pressure applied to the reservoir) with the catheter taped onto the skin and hidden from view with an opaque cover. The subject and the recovery room staff were blinded to whether an active device or placebo had been installed. At the time of discharge, the staff recorded how long the subject had been in the recovery room. The rationale for using recovery room time as an index of successful pain management was that, because all patients were ambulatory, none was released until pain was (in the nurse's opinion) acceptable for transfer to home care. Although time of release was also influenced by other factors, a high pain level would necessitate a longer stay in the recovery room. At discharge, each subject was asked to report subjective pain on a scale from 0 to 10. (A verbal scale, rather than a visual analog scale, is standard in our center because many patients either cannot see clearly immediately after surgery or are unable to mark a printed scale.) Each was instructed to keep a log of pain pill usage and was given instructions to perform pendulum exercises at least twice per day. Participants were scheduled for two follow-up visits: one on the second day after surgery and another at 7 to 10 days.

On the second day after surgery, the principal investigator (blinded to the group assignment) reviewed the pain pill log, asked for a subjective rating of pain (verbal scale from 0 to 10), and inquired about unexpected experiences. The dressing and the infusion device were both removed. At this point, the investigator became aware of the group assignment by observing whether it was a normal (percutaneous) or placebo installation. However, the subject and family members were asked to look away as the catheter was removed so that they would not see whether it was an active device or a placebo. Active range of motion of the shoulder was measured with a goniometer for abduction and forward flexion, both with the elbow extended.

At 7 to 10 days after surgery, the subject returned to the clinic and was again asked about subjective pain and unexpected experiences. Ranges of motion were measured, and the pain pill log was collected. Only then was the subject told whether the device was real or a placebo.

The infusion device was the PainPump (Stryker Instruments). Its reservoir was a 100-mL syringe with a spring-loaded plunger. In this study the reservoir was filled with 0.5% bupivacaine (with 1:200,000 epinephrine). At the time of installation, the plunger was released (except in placebo installations) and analgesic solution flowed continuously and passively. The flow rate was 2 mL/h, so the entire 100 mL was delivered over a period of 50 hours.

One surgeon performed all surgeries except for three that were done by a colleague. Before surgical intervention, 25 mL of 0.5% bupivacaine with epinephrine was injected into the subacromial space for preemptive analgesia. During surgery, subjects were given propofol (titrated) for general anesthesia, intramuscular ketorolac (30 mg), and intravenous narcotic as indicated. On completion of arthroscopy, an additional 25 mL of 0.5% bupivacaine was injected into the subacromial space. The infusion device (or placebo) and a chilled compressive dressing (Shoulder CryoCuff; Aircast, Summit, NJ) were applied in the operating room. After recovery, subjects were instructed on how to keep the dressing chilled and pressurized, were given a 5-day supply of oral ketorolac (10 mg every 6 hours), and were given 50 capsules of hydroxycodone with acetaminophen to be taken as needed for pain.

It had been determined in advance that approximately 25 subjects in each group would yield adequate power (β = .80) to distinguish differences of 1 SD for subjective pain, number of narcotic pills taken, and range of motion.

RESULTS

During a period of 8 months, 157 candidates were identified, of whom 29% were excluded, 38% declined participation, and 33% (52 subjects) were enrolled. Those who declined were not asked for a reason, but the investigators had the subjective impression that half of them did not want to return to the clinic for an extra visit and half were reluctant to be subjected to research. Two subjects were removed before completion of the study, because in one case there was a bloody drainage in the recovery room and the pump was removed to facilitate treatment. In the other case the catheter was accidentally severed in the subject's home. This left a study population of 50 subjects, 25 in each of the authentic and placebo groups.

Originally, glenohumeral surgeries were included, and in those cases, the catheter was inserted directly into the glenohumeral joint. After 17 glenohumeral subjects were enrolled (10 with the pump and 7 with placebo), it was decided to limit further enrollments to subacromial cases. This decision arose from three incidents in which the catheter was difficult to remove. In two of those, the catheter was stuck in place (presumably still in the glenohumeral space) and removal failed on the first attempt. After some manipulation of the shoulder, the catheter came free and was removed. In the third case manipulation of the shoulder failed to release the catheter, and removal ultimately required forceful, steady traction on the catheter with pain and distress for the patient. Among those subjects who had the catheter placed in the subacromial space, the catheter was easily removed in all cases.

The subjects ranged in age from 18 to 65 years, with a mean of 41 years. Of the 50 subjects, 34 were male and 16 female. There were no significant differences between groups (pump or placebo) with regard to age or sex.

Table I summarizes the outcomes of the analgesic infusion group versus the placebo group. The data in therein are listed separately for those who had subacromial surgeries and those who had glenohumeral procedures. If the data from the subacromial and glenohumeral cases were combined, the power of each statistic would be greater, but in fact, the additional power did not reveal any new relationships, so the combined data are not listed.

Table I Comparisons between analgesic pump and placebo for two different types of shoulder surgery

	Subacromial surgery		Glenohumeral surgery	
	Analgesic pump	Placebo	Analgesic pump	Placebo
Time in recovery room (min)	127 ± 40*	158 ± 32*	136 ± 26	146 ± 22
Time to first rescue pain pill (h)‡	7.3 ± 5.7	5.7 ± 3.7	2.8 ± 1.3†	7.3 ± 3.2†
Number of rescue pain pills in first 48 h	6.9 ± 5.7	6.0 ± 3.5	7.6 ± 6.0	8.0 ± 5.2
Number of rescue pain pills in first 5 d	9.1 ± 10.2	8.1 ± 5.3	13.8 ± 11.6	12.1 ± 8.3
Subjective pain at discharge (scale 0-10)	2.8 ± 2.0	2.5 ± 2.5	2.8 ± 2.3	1.3 ± 1.1
Subjective pain on day 2 (scale 0-10)	4.4 ± 2.9	3.0 ± 2.2	3.7 ± 2.4	3.9 ± 1.9
Subjective pain on day 9 (scale 0-10)§	3.5 ± 3.2	2.3 ± 1.7	2.8 ± 4.8	1.9 ± 2.3
Pain change, days 0-2 (scale 0-10)	1.6 ± 2.0	0.6 ± 2.9	0.9 ± 1.8	2.6 ± 1.9
Pain change, days 2-9 (scale 0-10)§	−0.9 ± 1.6	−0.8 ± 1.9	−0.8 ± 1.8	−2.0 ± 1.0
Abduction on day 2 (°)	48 ± 25	51 ± 25	29 ± 19	50 ± 60
Abduction on day 9 (°)§	106 ± 50	111 ± 41	62 ± 25	76 ± 55
Abduction change days 2-9 (°)§	57 ± 42	60 ± 39	36 ± 18	27 ± 37
Forward flexion on day 2 (°)	51 ± 27	45 ± 25	33 ± 28	56 ± 57
Forward flexion on day 9 (°)§	122 ± 58	124 ± 43	69 ± 22	78 ± 55
Forward flexion change, days 2-9 (°)§	68 ± 39	79 ± 49	37 ± 24	22 ± 24

*$P = .02$.
†$P = .005$.
‡Excludes 4 subjects who never took any rescue medication: 1 with glenohumeral surgery and wearing a pump, 1 with subacromial surgery and wearing a pump, and 2 with subacromial surgeries and placebo devices.
§"Day 9" actually refers to a range of days from the 7th to the 10th, with an average of 9.

Only two of the outcomes measures in Table I were statistically significant. First, subjects who had subacromial surgery spent significantly less time in the recovery room if they had an analgesic infusion device (mean, 127 minutes) instead of a placebo (mean, 158 minutes). Those in the placebo group were held in recovery for approximately 30 minutes longer ($P = .02$). Second, subjects who had glenohumeral surgery waited a significantly longer time before taking their first narcotic pain pill as a rescue medication if they had the placebo device (7.3 hours) rather than the analgesic infusion device (2.8 hours) ($P = .005$).

The remainder of the data in Table I provide no statistical evidence that the analgesic infusion pump was better than a placebo. More specifically, the pump did not decrease the demand for narcotic rescue medication, did not reduce subjective pain, and did not allow better active ranges of motion.

Many of the variables in Table I had a skewed distribution, raising a question of whether the *t* test was appropriate for comparing groups statistically. Therefore, the data in Table I were also analyzed by a nonparametric statistical test, the Mann-Whitney *U* test. The nonparametric method did not alter the statistical significance of any of the findings.

All subjects were asked whether they had any complaints. In the pump group the complaints were night pain, flushing and tenderness of skin, rebound pain after removal of the device (4), nausea (2), nausea on removal of the device, and a leaky catheter. In the placebo group, there were complaints of unbearable pain, night pain (2), neuropathic pain, pain after a fall, sore muscles after physical therapy, shoulder stiffness, headache, bruising, discomfort on a bicycle, sore elbow, nausea (2), urinary retention, itching around the dressing, and inconvenience of the device. This list does not provide any obvious pattern of complications, except for the 4 cases with rebound pain after the pump was removed.

DISCUSSION

This research was limited to only two classes of arthroscopic surgery: subacromial decompression and repairs of the glenohumeral labrum. The findings should not be extrapolated to other shoulder surgeries, such as repair of the rotator cuff, or to surgeries of other joints.

The proportion of subjects declining participation was relatively large (38%) and could be the source of some bias in the results. It might well be true that those who declined to participate would be less compliant than volunteers, more sensitive to irregularities in their lives, more suspicious about things they do not know or understand, and so on. These traits could also influence their perception of whether an infusion pump would ease their pain. In this study, reasons for declining were not recorded, and it remains an open question whether efficacy of the device might be related to psychological factors.

Another limiting factor is that the pump was studied against a background of multimodal pain control methods including intravenous and local injections of

antiinflammatories, anesthetics, and narcotics as well as oral analgesics and antiinflammatories and use of a cold compressive dressing. It may be that this background could mask a positive, but minor, efficacy of the infusion device.

When this study was designed, we considered using a more complete placebo—that is, an analgesic pump filled with saline, with the catheter installed into the wound, and saline delivered at the normal rate. We decided to use the placebo without installation of the catheter and no fluid delivery, because it would reduce the risk of infection or other complications in the group not receiving the hypothetical benefit of bupivacaine infusion.

Since the introduction of disposable infusion pumps in the early 1990s, there have been a few reports in the critically reviewed literature that claim benefits[1,3-5,7] and none that deny them. However, we have the impression that many surgeons are influenced by anecdotal evidence favoring use of the pumps. This is not surprising considering that pain perception and pain management are both subjective and the main outcome is whether the patient is satisfied with the pain and its management.

In conclusion, we strove to verify whether a disposable anesthetic infusion pump was cost-effective in our surgery center. The perceived costs were the price of the device, risk of infection, risk of device failure, additional effort on the part of the surgical team, and inconvenience of wearing the device for 2 days. The potential benefits were reduced subjective pain, reduced demand for narcotic rescue medication, and quicker recovery of shoulder motion. We did not find any notable benefits except that use of the pump was correlated with a shorter time in the recovery room, as compared with placebo. Thus, the cost of these devices is not currently justifiable.

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