

Requirements for Muscle Relaxants during Radical Retropubic Prostatectomy

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Background: **The need for the routine use of muscle relaxants to provide an adequate surgical field for intraabdominal surgery has not been established. This study tested the hypothesis that vecuronium decreases the frequency of unacceptable operating conditions for patients undergoing radical retropubic prostatectomy who are anesthetized with isoflurane and fentanyl.**

Methods: **After obtaining informed consent, patients in this blinded, placebo-controlled study were randomized to receive either an infusion of vecuronium or saline (placebo) beginning 5 min after fascial incision during the maintenance of anesthesia with at least 1 minimum alveolar concentration end-tidal isoflurane and fentanyl infusion. The surgical field was graded from 1 (excellent) to 4 (unacceptable) by the surgeons at 15-min intervals. If a grade 4 rating occurred (defined as a treatment failure), the patient received rescue vecuronium.**

Results: **A total of 120 patients are included in this report (59 in the vecuronium group and 61 in the placebo group). The frequency of treatment failure in the placebo group was 17 of 61 (27.9%) versus 1 of 59 (1.7%) in the control group who received vecuronium ($P < 0.001$). Thirty-eight patients (62.3%) in the placebo group and 52 patients (88.1%) in the vecuronium group had surgical field ratings of ≤ 2 (good to excellent) at each time assessed throughout the procedure.**

Conclusion: **The study hypothesis was confirmed. However, an isoflurane–fentanyl anesthetic alone produced a good to excellent surgical field in approximately two thirds of patients undergoing radical retropubic prostatectomy without the use of muscle relaxants. Thus, the routine use of muscle relaxants in adequately anesthetized patients undergoing this procedure may not be indicated. (Key words: Laparotomy; neuromuscular blocking drugs; train-of-four; vecuronium.)**

NONDEPOLARIZING muscle relaxants are used routinely for many procedures in modern anesthetic practice. The indications for their use have expanded considerably from the original goal of providing adequate muscle relaxation to facilitate surgical exposure for selected surgical procedures. In particular, they are often used to ensure patient immobility in lieu of higher doses of general anesthetic drugs and, indeed, can be effective for this purpose. However, like any drug, their use is not without risk. Beyond the various effects of some agents on other organ systems with short-term administration, prolonged effects in the postoperative period may lead to pulmonary complications.[1] Furthermore, cases of intraoperative awareness have occurred in patients receiving muscle relaxants who are not able to move in response to surgical stimulation.[2,3] Some investigators suggest that to minimize the possibility of awareness, muscle paralysis should be avoided unless absolutely necessary.[4,5]

It would thus seem important to define clear indications for the use of these agents. However, there is surprisingly little information regarding the actual requirement for these agents to provide adequate surgical exposure for procedures such as intraabdominal surgery. Although there is no doubt that pharmacologic paralysis can eliminate abdominal muscle tone, it is not clear whether paralysis is routinely required to provide adequate surgical conditions in patients who are adequately anesthetized using modern techniques. Volatile anesthetics themselves produce muscular relaxation.[6] There is also evidence that, in animals who are adequately anesthetized, laparotomy in fact inhibits abdominal muscle activation,[7] an action that should promote surgical exposure. If adequate surgical conditions can be provided in many patients without muscle relaxants, their routine use may not be indicated.

The purpose of this study was to test the hypothesis that vecuronium decreases the frequency of unacceptable operating conditions, as assessed by surgeons, in patients undergoing radical retropubic prostatectomy (RRP) who are anesthetized with isoflurane and fentanyl. This hypothesis was tested using a randomized, blinded, placebo-controlled design. A secondary aim was to determine the frequency with which adequate surgical conditions could be achieved without the use of muscle relaxants in these patients.

Methods

The study protocol was approved by the institutional review board (Mayo Clinic, Rochester, MN), and written informed consent was obtained from enrolled patients. The study population included male patients, American Society of Anesthesiologists physical status I or II, between the ages of 18 and 70 yr, who were scheduled to undergo RRP. Patients were excluded if they had any contraindication to any element of the study anesthetic protocol (*e.g.*, a history of malignant hyperthermia).

After enrollment, the patients were randomly assigned to one of two treatment groups using a computer-generated randomization schedule. An anesthesia care team, consisting of either an anesthesia resident or a certified

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registered nurse anesthetist and an attending anesthesiologist, was responsible for the clinical care of the patient during the study period. This team and all other personnel providing clinical care, including the surgeons, were blinded to group assignment throughout the study. The anesthesia care team was primarily responsible for patient safety and could elect to discontinue patient participation in the study at any time. A second anesthesiologist served as the investigator.

Standard monitors were applied, and intravenous access was obtained. All patients were preoxygenated before induction, which was accomplished with fentanyl 3–5 μg/kg, followed by 4 mg/kg sodium thiopental and 1.5 mg/kg succinylcholine to facilitate endotracheal intubation. After intubation, the lungs were mechanically ventilated with a 50:50 air:oxygen mixture. Patients were ventilated to achieve a target end-tidal carbon dioxide partial pressure of less than 30 mmHg to minimize spontaneous movement of the diaphragm. Isoflurane was administered in sufficient inspired concentration to achieve an end-tidal concentration of 1 minimum alveolar concentration (1.2%) by the time of incision and to maintain at least this concentration throughout the procedure. A continuous fentanyl infusion of 2 $\mu g \cdot kg^{-1} \cdot h^{-1}$ was also maintained. Decreases in systolic blood pressure more than 30% below preoperative values or less than 90 mmHg were treated with fluid bolus doses of 250 ml crystalloid and/or ephedrine 10 mg intravenously. After incision, the isoflurane concentration could be adjusted at the discretion of the anesthesia provider with the goal of maintaining an end-tidal concentration of at least 1.2%. Patients who had significant hemodynamic or movement responses to surgical stimulus were treated with additional bolus doses of fentanyl (1 μg/kg) and/or increases in the inspired concentration of isoflurane at the discretion of the anesthesia team.

After intubation, the investigator attached a strain gauge (Grass FT-03, Quincy, MA) to the right thumb to measure the force response of the adductor policis muscle in response to maximal ulnar nerve stimulation according to standard techniques.[8] The response to the standard train-of-four (TOF) stimulus (2 Hz) was recorded at 1-min intervals throughout the procedure. Both the anesthesia care team and the surgical team were blinded to this assessment by draping the hand. In all cases, four strong twitches were present by the time of surgical skin incision (at least 15 min after intubation), indicating the dissipation of succinylcholine effect.

After incision of the abdominal fascia through a low midline incision, the surgeon was asked by the investigator to give a surgical field rating using a numerical scale of 1–4. A grade 1 field (excellent) was one in which the lower abdomen was relaxed, and surgical exposure was easily obtained. A grade 2 field (good) was one in which abdominal relaxation and surgical exposure were adequate but not optimal. A grade 3 field

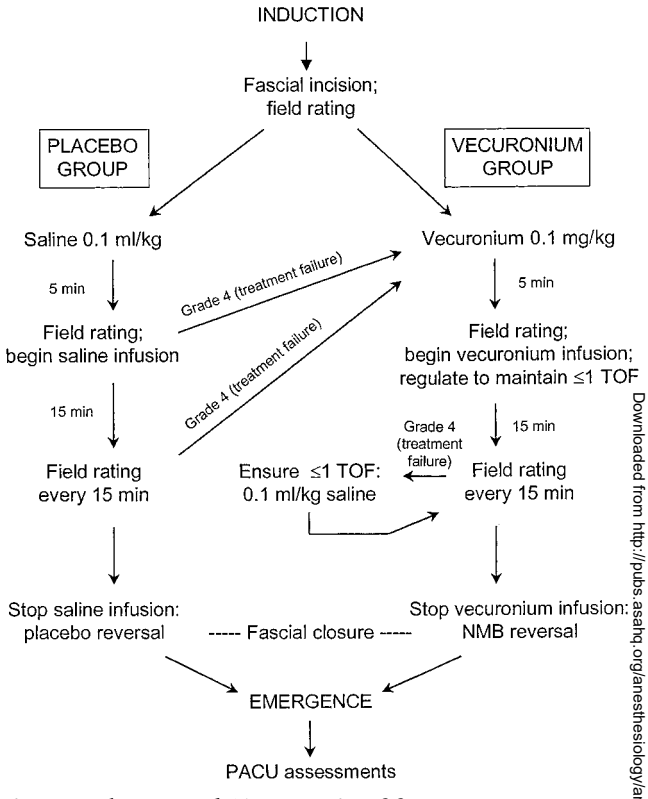

Fig. 1. Study protocol. TOF = train of four; NMB = neuromuscular blockade; PACU = postanesthesia care unit. "Grade 4" refers to a surgical field rating by surgeons.

(acceptable) was one in which exposure was moderately difficult to obtain but acceptable. A grade 4 field (poor) was one in which the surgical exposure was unacceptable to the surgeon because of abdominal or diaphragm muscle tone.

After this surgical field assessment, the patient was given a bolus dose of either normal saline (0.1 ml/kg, placebo group) or vecuronium (0.1 mg/kg, vecuronium group) by the investigator (fig. 1). Five minutes after administration of this bolus dose, the investigator asked the surgeon to again rate the surgical field and began an IV infusion of saline or vecuronium. For vecuronium, the initial rate was 1 $\mu g \cdot kg^{-1} \cdot min^{-1}$ and was titrated to achieve one twitch or less in response to TOF stimulation, a condition considered to provide adequate surgical muscle relaxation according to standard practice.[8] For normal saline, random adjustments to the infusion rate were made by the investigator to simulate titration. The surgeon was then asked to rate the surgical field at 15-min intervals.

If the surgical field was deemed unacceptable (grade 4 condition) at any time after the administration of the study drug bolus dose, the patient was considered a treatment failure. If the patient was in the placebo group, a 0.1-mg/kg bolus dose of rescue vecuronium was administered, and the saline infusion was changed to a vecuronium infusion after 5 min. If the procedure was within approximately 30 min or less of completion, the

patient received 0.05 mg/kg, and an infusion was not begun. If the patient was in the vecuronium group, the investigator confirmed the presence of adequate relaxation (one or fewer twitches in response to the TOF stimulation) and if necessary increased the infusion rate of the vecuronium to achieve this. The patient was also given 0.1 ml/kg of normal saline.

The fentanyl infusion was discontinued 30 min before the estimated completion of the procedure. The vecuronium or saline infusion was discontinued at the beginning of fascial closure. Once the fascia was completely closed, the patients received either 0.07 mg/kg neostigmine with 0.02 mg/kg glycopyrrolate (vecuronium group) or an equivalent volume of normal saline (placebo group). The surgeons were asked to give a final field assessment at the time of fascial closure. Discontinuation of the isoflurane was then at the discretion of the anesthesia care team. The investigator informed the anesthesia care team that a normal TOF response was present before extubation. The timing of extubation, transfer to the postanesthesia care unit (PACU), and PACU management of the patient was at the discretion of the anesthesia care team. In the PACU pain scores were obtained either on admission or when the patient could first respond using a standard visual analog scale. Episodes of emesis within the first 4 h after extubation were noted.

Statistics

Patient and procedural characteristics were compared between treatment groups using the rank sum test for continuous variables and the chi-square test for discrete variables. Treatment failure was defined as a grade 4 surgical field rating occurring at any time after the initial assessment on fascial incision (*i.e.*, $\geq$ 5 min after fascial incision). One other instance of treatment failure was defined as described below. The frequency of treatment failure was compared between groups using the Fisher exact test, and an exact 95% confidence interval (CI) for the percentage of treatment failure was calculated for each group. For this investigation, a sample size of 60 patients per group provided a power of 90% to detect any frequency of treatment failure in excess of 25% for placebo patients, assuming a 5% frequency in the vecuronium group. Pain scores at PACU admission were compared using the rank sum test. The percentage of patients that experienced emesis during the first 4 h after surgery was compared between treatment groups using the Fisher exact test. In all cases, P values ≤ 0.05 were considered statistically significant.

Results

There were 124 patients randomized (62 vecuronium, 62 placebo). Of these enrolled patients, four were excluded after randomization but before administration of the study drug: two because of intraoperative violations of protocol (administration of narcotics other than fentanyl by the anesthesia team before surgical incision), one patient in whom RRP was not performed after laparotomy because of previously undiagnosed metastatic disease, and one patient who had an unexpectedly difficult airway and required prolonged attempts at intubation. Thus, the analysis included 120 patients (59 vecuronium, 61 placebo).

Table 1. Patient Characteristics

Characteristic	Placebo (N = 61)	Vecuronium (N = 59)
Age (yr)		
Median	63	63
Mean ± SD	62.3 ± 7.0	62.8 ± 7.6
Range	46–74	45–76
Weight (kg)		
Median	86	87
Mean ± SD	85 ± 11	87 ± 11
Range	59–122	63–112
Body Mass Index (kg/m^2)		
Median	26.7	27.7
Mean ± SD	27.6 ± 3.2	27.9 ± 3.1
Range	20.8–36.8	21.3–37.9
Preoperative hypertension (%)	16	24

The patient characteristics did not differ significantly between the two groups (table 1). Procedural characteristics such as the end-tidal carbon dioxide partial pressure, end-tidal isoflurane, total fentanyl dose, and total dose of ephedrine used in those patients who required it (34 [56%] and 35 [59%] patients in placebo and vecuronium groups, respectively) were not significantly different between groups (table 2). Anesthesia time and the time from skin closure to recovery room admission were not different between groups (table 2).

The frequency of treatment failure was 17 of 61 (27.9%; 95% CI, 17.2–40.8%) for patients receiving placebo compared with 1 of 59 (1.7%; 95% CI, < 0.1–9.1%) for patients receiving vecuronium ($P < 0.001$). Fifteen patients defined as treatment failures in the placebo group received rescue vecuronium after the surgeon judged the surgical field to be poor. Two additional patients in the placebo group were also considered to have experienced treatment failure. One patient experienced a transient grade 4 field rating that resolved to the surgeon's satisfaction before rescue vecuronium could be administered, and did not receive vecuronium. One other patient in the placebo group developed hypotension after surgical hemorrhage. At the request of the clinical anesthesia team, the patient's treatment assignment was revealed, and further data were not collected for this patient. The anesthesia team elected to administer cisatracurium and additional narcotics, decrease the inspired isoflurane concentration, and successfully performed volume resuscitation with packed erythrocytes. This patient, the only one who required transfusion of

Table 2. Procedural Characteristics

Characteristic	Placebo (N = 61)	Vecuronium (N = 59)
End-tidal CO_2* (mmHg)	26 ± 3	26 ± 3
End-tidal isoflurane* (%)	1.3 ± 0.1	1.3 ± 0.1
Fentanyl infusion* ($\mu g \cdot kg^{-1} \cdot hr^{-1}$)	2.2 ± 0.4	2.2 ± 0.4
Total fentanyl dose† (μg)	712 ± 145	687 ± 143
Total ephedrine dose‡ (mg)	19 ± 14	16 ± 10
Anesthesia time§ (min)	144 ± 27	142 ± 31
Emergence time‖ (min)	21 ± 7	19 ± 6

Values are mean ± SD.

* Characteristic was measured at fascial opening, 5 min after administration of the study drug, and every 15 min thereafter until the time of fascial closure. Data were analyzed using the average measurement during this time period for each patient. † Data were missing for one patient in the placebo group and three patients in the vecuronium group. ‡ Ephedrine was administered in 34 placebo patients and 35 vecuronium patients. Total dose information was missing for 1 of the 35 vecuronium patients administered ephedrine. § Anesthesia time was defined from anesthetic induction to completion of skin closure. ‖ Emergence time was defined from the completion of skin closure to postanesthesia care unit admission and included the time needed for tracheal extubation and for survey radiology of the abdomen; data were missing from one placebo patient and three vecuronium patients.

CO_2 = carbon dioxide.

erythrocytes, was classified as experiencing treatment failure for purposes of data analysis.

Overall, 38 of 61 patients (62.3%; 95% CI, 49.0–74.4) in the placebo group and 52 of 59 patients (88.1%; 95% CI, 77.1–95.1) in the vecuronium group received maximum field scores ≤ 2 (*i.e.*, good to excellent) at each assessment throughout the course of the procedure (fig. 2). For the 15 patients in the placebo group who received rescue vecuronium, at the first surgical field assessment after the administration of the vecuronium (at a time when the response to TOF stimulation was absent), 8 had a field rating of 1, 6 had a field rating of 2, and 1 had a field rating of 3. Thus, some of these patients had less-than-optimal conditions even when fully paralyzed.

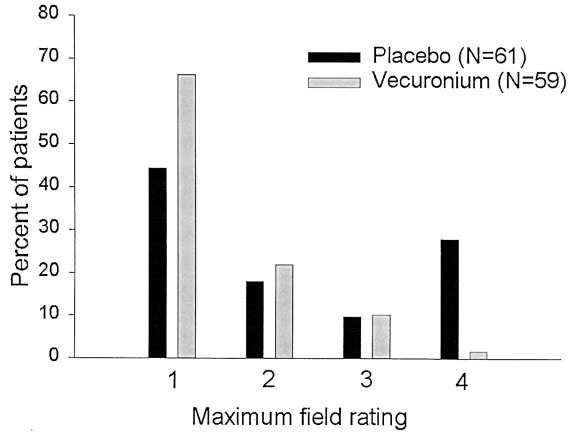

Fig. 2. Distribution of the maximum field rating recorded after fascial incision over the course of surgery for each patient. The field rating was recorded at 5-min intervals after administration of study drug and every 15 min thereafter until fascial closure. A field rating of 4 was assigned to one placebo patient who was classified as a treatment failure because of intraoperative events other than inadequate surgical field as described in the text. For patients who did not experience a treatment failure, the data presented correspond to the maximum field rating recorded.

The distribution of field ratings at each assessment is given in table 3. The mean field rating at the time of fascial incision (before the administration of vecuronium or placebo) was not significantly different between groups (2.4 ± 1.0 [mean ± SD] and 2.1 ± 1.0 for placebo and vecuronium groups, respectively), although 11 of 61 patients (18%) in the placebo group compared with 5 of 59 patients (9%) in the vecuronium group had a field rating of grade 4 at this time ($P = 0.18$). In the placebo group, 7 of these 11 patients (64%) went on to experience treatment failure, with 5 receiving rescue vecuronium for continued grade 4 conditions assessed 5 min after fascial incision. The sole treatment failure in the vecuronium group was given a field rating of 4 at the time of fascial incision that persisted for 20 min after the administration of vecuronium, despite no twitch in response to TOF stimulation. Overall, for the 17 placebo patients experiencing treatment failure, the median time from fascial incision to failure was 17 min.

In the postoperative period, there was no significant difference between groups in pain scores or the frequency of emesis (table 4). No patient suffered other postoperative complications.

Discussion

We confirmed the hypothesis that vecuronium decreases the frequency of unacceptable operating conditions in patients undergoing RRP who are anesthetized with isoflurane and fentanyl. However, good to excellent surgical conditions for the duration of the procedure were achieved in approximately two thirds of patients even without the use of muscle relaxants.

In their classic review of techniques to monitor neuromuscular function, Ali and Savarese[8] stated that 90–95% suppression of the single-twitch response to supramaximal ulnar nerve stimulation provides satisfactory surgical relaxation during nitrous oxide anesthesia. Of the references provided to support this assertion, only one examines this question directly. de Jong[9] examined 25 adult patients undergoing intraabdominal surgery anesthetized with endotracheal nitrous oxide and halothane at "moderate to light surgical levels." Similar to our protocol, the surgical field was rated in the absence of muscle relaxants after fascial incision and then after the incremental administration of succinylcholine, tubocurarine, or gallamine. The surgeons were not blinded as to drug administration. They found that abdominal muscle relaxation, as estimated by the clinical judgment of surgeons, increased with increasing doses of relaxant. Relaxation was correlated with the electromyograph response to peripheral nerve stimulation. It is important to

Table 3. Summary of Field Ratings

Minutes after Fascial Opening	Placebo (N = 61)						Vecuronium (N = 59)					
	1	2	3	4	Previous Rescue	Missing	1	2	3	4	Previous Rescue	Missing
0	23	30	30	18	0	0	39	20	32	9	0	0
5	51	23	13	5	7	2*	66	24	9	2	0	0
20	56	25	0	3	16	0	81	15	3	0	0	0
35	61	16	2	3	18	0	85	15	0	0	0	0
50	56	16	0	0	25	3	85	14	0	0	0	2
65	53	15	0	0	25	8	71	10	0	0	0	19

Values are the percentage of each group of patients at each specified time who received field ratings (1–4), who were administered "rescue" vecuronium since fascial opening (previous rescue), or for whom field ratings were not obtained because the fascia had been closed (missing).

* Field rating was not obtained in one patient at this time who had just been administered "rescue" vecuronium.

note that, as was customary in this era, the patients were breathing spontaneously before the administration of muscle relaxants, with ventilatory assistance then provided as respiratory efforts were suppressed. Halothane anesthesia produces significant phasic expiratory activity in abdominal muscles,[10,11] activity that would interfere with surgical exposure. Indeed, it is apparent from other work dating from this period that one major effect of relaxation on abdominal muscle electromyogram is to abolish this phasic expiratory muscle activity, an action that can also be accomplished by hyperventilation (which we used in our study).[12] Tonic activation of abdominal muscles has also been observed during light anesthesia maintained with nitrous oxide and supplemental intermittent thiopental, activation that increases with surgical stimulation and that is abolished by muscle relaxants.[13] However, tonic activation has not been observed during anesthesia produced by volatile agents.[11] These results suggest that extrapolation of recommendations regarding the magnitude of paralysis necessary for adequate operating conditions based on these early studies to current practice, which uses different drugs, often with controlled ventilation, which eliminates respiratory motion, should be performed with caution.

Table 4. Postoperative Assessments

Outcome	Placebo (N = 61)	Vecuronium (N = 59)	*P**
Pain†			NS
Median	1	1	
Mean ± SD	3.0 ± 2.8	2.8 ± 3.0	
Emesis during first 4 h (%)	9.8‡	5.1	NS
Postoperative complications§ (%)	0.0	0.0	NS

* Treatment groups were compared using the rank sum test for continuous variables and the Fisher exact test for categorical variables. † Pain was assessed at the time of PACU admission using a visual analog scale. Pain information was missing for two placebo patients and three vecuronium patients who were too somnolent to be assessed. ‡ Two of the six patients in the placebo group who experienced emesis had been administered "rescue" vecuronium. § Postoperative complications include reintubation, aspiration, hypoxemia, intractable pain, intractable nausea or emesis, intensive care unit admission, and death.

PACU = postanesthesia care unit.

In our study, we attempted to provide a similar anesthetic to the two groups in every respect except for the use of vecuronium so that we could evaluate its impact on surgical conditions as an independent factor. Measures such as isoflurane concentration, fentanyl dose, and initial postoperative pain were indeed comparable between groups. However, although not statistically significant, there was a tendency toward a greater proportion of patients in the placebo group having grade 4 conditions at fascial incision, a finding we can explain only by interpatient variability, as the anesthetic management in the two groups was identical to this point. Because many of these patients in the placebo group eventually required rescue vecuronium, this factor may bias our results toward overestimating the benefit of vecuronium. Nonetheless, vecuronium significantly increased the proportion of patients in whom at least adequate (≤ grade 3) surgical field ratings were maintained throughout the procedure, from 72% (placebo group) to 98%. Of interest, several patients who had received vecuronium (34%) were still rated as having less than excellent (grade 1) conditions, suggesting that factors other than muscle tone can contribute to suboptimal surgical exposure.

Although it is not unexpected that a muscle relaxant can improve the surgical field, the majority of patients in the placebo group maintained good to excellent conditions (field rating ≤ 2) without it. This raises the clinical question of the risks and benefits of the routine administration of muscle relaxants to patients undergoing abdominal surgery such as RRP. Harold Griffith, one of the pioneers in the investigation of these drugs, expressed concern over their use as a substitute for adequate anesthesia, stating that paralyzing agents ". . .should not be used indiscriminately because the inexperienced anesthetist is too inefficient to obtain adequate muscle relaxation by ordinary procedures."[4] The risks of relaxants depend to some extent on the specific drug, but include actions on other organ systems, such as cardiopulmonary effects secondary to histamine release produced by some drugs, incomplete postoperative reversal of block-

ade,[1,14] and the impairment of an important clinical sign of inadequate anesthesia (*i.e.*, patient movement). Even with at least one member of the newer generation of shorter-acting drugs (mivacurium), residual paralysis remains a concern.[15] Recent analysis of closed-claims data showed that the use of muscle relaxants is an independent risk factor for claims of intraoperative awareness compared with other types of claim,[2] a finding that suggests, but does not prove, that their use may increase the risk of awareness.[5] There are also concerns regarding the possible complications arising from agents used to reverse muscle relaxants, such as an increased frequency of postoperative emesis.[16] However, like other investigators,[17,18] we found no evidence that the use of reversal agents increased the frequency of emesis.

Although our study shows that many patients did not require muscle relaxants to achieve adequate surgical operating conditions, muscle relaxants may have benefit if their use can minimize adverse consequences of other drugs used in the perioperative period. For example, paralysis may permit use of lower doses of general anesthetic agents, which may speed recovery and avoid side effects of these agents, such as cardiovascular depression. Indeed, approximately half of the patients in our study required small doses of vasopressors, usually in the period before surgical incision. Thus, consideration of these factors must also be balanced against the risk of the muscle relaxants themselves. Reliable estimates of this risk in clinical practice are not available, but the frequency of significant adverse events associated with muscle relaxants is probably low enough that a large clinical trial would be necessary to definitively answer the question. A cost–benefit analysis related to the use of relaxants is beyond the scope of our study but would be of interest as a topic of future research.

These results should be extrapolated to other settings with caution. Each specific surgical procedure and each individual surgeon present their own requirements for adequate operating conditions. We chose to study RRP because at our institution this procedure is performed with a standardized surgical technique, is of moderate duration, and is associated with a low frequency of significant intraoperative complications, such as hemorrhage requiring transfusion (1 of 120 patients in our series). These features may not be characteristic of RRP performed in other institutions. Other factors, such as patient gender with associated differences in muscle mass, may also be important. For some surgical procedures, the risk of causing surgical trauma if any movement occurs may dictate the routine use of these agents. Our results should be interpreted as a demonstration in a specific surgical setting that, although muscle relaxants significantly decrease the frequency of unacceptable surgical field ratings, adequate operating conditions can be obtained in many patients without muscle relaxants. These findings suggest that anesthesiologists should at least consider whether muscle relaxants should be used routinely in some procedures, or whether more selective application when inadequate surgical conditions are actually present might be more appropriate. Good communication between anesthesiologist and surgeon must be maintained if this approach is to be successful.

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