Contemporary Management of Hemorrhage After Minimally Invasive Radical Prostatectomy

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OBJECTIVE To describe contemporary management and outcomes of patients experiencing postoperative hemorrhage after minimally invasive radical prostatectomy.

MATERIALS AND METHODS We retrospectively analyzed data from patients who underwent minimally invasive radical prostatectomy at our institution between January 2010 and January 2017. Clinically significant hemorrhage was defined as a decrease in hemoglobin of ≥30% or 4 g/dL from preoperative to 4 or 14 hours postoperative measurement, receiving a blood transfusion within 30 days, or undergoing a secondary procedure to control bleeding. Patients were analyzed in 3 groups: (1) serially monitored only, (2) received a blood transfusion, and (3) underwent a secondary procedure. Outcomes included imaging studies performed, length of stay, emergency room visits, hospital readmissions, complication rates, and functional outcomes.

RESULTS Of 3749 men, 4% (151/3749) had clinically significant hemorrhage, 1.6% (60/3749) received a transfusion; 0.32% (12/3749) underwent a secondary procedure to control bleeding. In a 30-day composite outcome, increased healthcare utilization (emergency room visit, readmission, or Grade ≥3 complications), was seen in 25% of the serial monitoring group, 65% of the transfusion group, and 100% in the secondary procedure group. This rate in 3598 men without hemorrhage was 12.5%. One-year erectile function was poorest in men who underwent a secondary procedure. Urinary functional outcomes were similar in the 3 groups.

CONCLUSION Most patients experiencing clinically significant hemorrhage will stabilize without transfusion, and a very small fraction require secondary intervention. Patients experiencing milder bleeding events utilized additional healthcare resources at approximately twice the rate of those who did not, warranting appropriate counseling and postoperative monitoring. UROLOGY 130: 120–125, 2019. © 2019 Elsevier Inc.

Robotic-assisted radical prostatectomy has largely supplanted both the laparoscopic and open retropubic approaches for prostate cancer surgery, with at least 85% of prostatectomies performed on the da Vinci platform (Intuitive Surgical, Sunnyvale, CA) in the United States.[1] While the literature varies on oncologic and functional outcomes, the data clearly demonstrate favorable outcomes for minimally invasive radical prostatectomy (MIRP) relative to open RP (ORP) with respect to mean blood loss and transfusion rates.[2,3] Although the adoption of minimally invasive techniques has rendered significant hemorrhage an infrequent occurrence, it remains a troubling complication of MIRP.[2]

The clinical management of hemorrhage after MIRP is not well described despite wide anecdotal and institutional experience. With ORP, Hedican and Walsh reported that most men could be managed expectantly, but advocated for early exploration in those requiring transfusion.[4] More recently, several case series have described the feasibility of minimally invasive exploration as well as angioembolization to control postoperative hemorrhage.[5-9] Despite these reports, decision-making criteria with respect to diagnostic imaging and therapeutic intervention have not been well established. Clinical management is often based on prior anecdotal experience with little evidence to guide these important decisions.

We aimed to provide a contemporary description of postoperative hemorrhage in patients following MIRP

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with a specific focus on describing management strategies, healthcare utilization, complications, and functional outcomes in these patients.

MATERIALS AND METHODS

Using a prospectively maintained surgical database, we retrospectively reviewed data from 3749 patients who underwent a complete MIRP (either laparoscopic or robot-assisted) by 1 of 12 surgeons at Memorial Sloan Kettering Cancer Center between January 2010 and January 2017. Institutional Review Board approval was granted. Clinically significant hemorrhage was defined as any one of the following: a decrease in hemoglobin of ≥30% or 4 g/dL, receiving a blood transfusion within 30 days postoperatively, or undergoing a secondary procedure to control hemorrhage. The hemoglobin criterion was satisfied based on a ≥30% or 4 g/dL decrease in hemoglobin levels between preoperative and 4 hours postoperative, preoperative and 14 hours postoperative, or 4 hours postoperative and 14 hours postoperative evaluations. Use of this trigger point is based on institutional data currently in preparation for publication which shows that for patients requiring postoperative transfusion for symptomatic and hence clinically significant bleeding following MIRP, the mean Hgb decrease at the point of requiring transfusion was 33.1% (22.6%, 38.6%). The blood transfusion and the secondary procedure criteria were limited to 30 days postoperatively.

Our initial cohort comprised 190 patients who met any of these initial criteria for clinically significant hemorrhage. Of these patients, 3 were considered anemic preoperatively (hemoglobin <13 g/dL) and were excluded. An additional 34 patients met our hemoglobin criterion initially but had a subsequent in-hospital blood draw that normalized outside of this range and were excluded. The rationale for this was to exclude any spuriously low hemoglobin values that may have been secondary to hemodilution in the early postoperative period. Two additional patients who underwent concomitant colorectal resection were also excluded. The final cohort comprised of 151 patients.

These patients were stratified into 3 clinical management groups: (1) those who were serially monitored and did not receive a blood transfusion, (2) those who received a blood transfusion, and (3) those who underwent a secondary procedure to control hemorrhage. Outcomes of interest included radiologic imaging to assess hemorrhage, repeat surgical or interventional radiology procedures, length of stay, 30-day returns to the emergency room, 30-day readmissions, 30-day complications (Clavien-Dindo classification)[10], and urinary and erectile functional outcomes.

As part of the routine care at our institution, patients were contacted to complete a web-based survey assessing self-reported erectile and urinary function at regular intervals postoperatively. The erectile function domain is the International Index of Erectile Function-6 (IIEF-6)[11]. Potency was defined as an IIEF-6 score of ≥22 (range 1-30). The urinary function domain consists of 5 questions assessing stress, urgency, urinary continence, and urinary bother.[12] Continence was defined as a urinary domain score of ≥17 (range 0-21). For patients who did not answer the corresponding surveys for any time point but reported being continent or potent in an earlier survey, this result was carried forward. Similarly, patients who reported incontinence or erectile dysfunction at a later survey were assumed to lack function in earlier surveys that they did not complete. We estimated postoperative 3-, 6-, and 12-month potency and continence within each treatment group. All statistical analyses were conducted using STATA 15.0 (StataCorp, College Station, TX).

RESULTS

Patient characteristics are summarized in Table 1. Of 3749 men, 151 (4%; 95% confidence interval 3.4%-4.7%) who underwent MIRP during the study period met our definition of clinically significant hemorrhage. Ninety-one of these men were managed with serial observation and did not require blood transfusion. The remaining 60 men received a transfusion (40% of men meeting our definition of clinically significant hemorrhage; 95% confidence interval 32%-48%; 1.6% of all men who underwent MIRP). Among these men, the median number of units transfused was 2 (interquartile range [IQR] 2-3). Twelve men underwent a secondary procedural intervention to control hemorrhage, all of whom received a blood transfusion and all of whom showed signs of hemodynamic instability. Men who remained hemodynamically stable were either monitored or transfused, then monitored, until stability was confirmed clinically. Most men underwent a robotic-assisted procedure (87%), and the remaining 13% underwent laparoscopic radical prostatectomy.

Postoperative hemoglobin values for the 3 clinical management groups are summarized in Table 2. As expected, the median- and minimum-observed hemoglobin values in the postoperative period were lowest in the group that underwent procedural intervention to control hemorrhaging, reflecting increased severity of blood loss.

Radiologic imaging performed to evaluate hemorrhaging is presented in Supplemental Table 1. Seven percent of men in the serial monitoring group had abdominopelvic imaging performed compared with 33% in the transfusion group and 25% in the procedural intervention group. All abdominopelvic imaging was done using CT with intravenous contrast alone or with oral contrast. CT angiography was performed in 3 men (12% of those who had imaging). Imaging most commonly revealed pelvic/resection bed hematoma, with or without hemoperitoneum.

The intraoperative findings among patients who underwent surgical exploration for bleeding are described in Table 3. Eight of 11 patients underwent exploratory laparotomy, 2 underwent laparoscopic exploration, and 1 underwent robotic exploration. In 7 cases of surgical exploration, no source of bleeding was identified. Sources of hemorrhaging were identified stemming from the dorsal venous complex (DVC), an accessory pudendal artery, obturator artery, and the neurovascular bundle. Among men requiring intervention, 9 underwent robotic prostatectomy and 3 underwent laparoscopic prostatectomy as initial surgery.

Healthcare utilization for the 3 clinical management groups is presented in Table 4. The risk of each of the adverse outcomes of interest was greatest in patients who required a secondary procedural intervention to control hemorrhaging. Length of stay, 30-day emergency room presentations, hospital readmissions, and major complications (Grade ≥3) were all highest in this group. These findings are summarized by a 30-day composite outcome for healthcare utilization (ER visits, hospital readmissions, or major complications), which was met in 25% of the serial monitoring group and 65% of the transfusion group. As a benchmark comparison, the rate in 3598 men without hemorrhage from the original cohort of 3749 was 12.5% (10% visited the ER, 6% were readmitted, and 2% had major complications). A detailed listing of complications is presented in Supplemental Table 2.

Table 1. Patient characteristics in men with postoperative hemorrhage. Data presented as median (interquartile range) and frequency (%).

Characteristics	(*n* = 151)
Age at MIRP	62 (57-66)
PSA (ng/dL) (*N* = 150)	6.2 (4.3-9.1)
Clinical stage	
cT1	85 (56%)
cT2	46 (30%)
cT3	7 (4.6%)
Unknown	13 (8.6%)
Gleason Grade Group on biopsy	
1	32 (21%)
2	66 (44%)
3	26 (17%)
4	15 (10%)
5	11 (7.3%)
Unknown	1 (0.7%)
ASA score	
1	2 (1.3%)
2	75 (50%)
3	74 (49%)
Minimally invasive surgical approach	
Robotic	132 (87%)
Laparoscopic	19 (13%)
Pathologic stage	
pT2	84 (56%)
pT3	64 (42%)
pT4	3 (2.0%)
Gleason Grade Group at MIRP pathology	
1	17 (11%)
2	81 (54%)
3	36 (24%)
4	5 (3.3%)
5	10 (6.6%)
Unknown	2 (1.3%)
Extraprostatic extension	67 (44%)
Positive surgical margin	46 (30%)
Nerve-sparing status	
None	16 (11%)
Unilateral	28 (19%)
Bilateral	101 (67%)
Unknown	6 (4.0%)
Lymph node dissection	125 (83%)
Lymph node invasion*	12 (10%)
Extended lymph node dissection*	89 (71%)
Unknown	2 (1.6%)
Number of total nodes removed*	15 (10-20)
Number of positive nodes found*	0 (0-0)
Operating room time (min) (*N* = 123)	227 (196-257)
Prostate volume (*N* = 136)	39 (28-52)
Potent at baseline	61 (40%)
Unknown	21 (14%)
Previous abdominal surgery	20 (13%)
Anticoagulant	4 (2.6%)
Aspirin	32 (21%)
Number of total nodes removed*	
1-5	7 (5.6%)
6-10	27 (22%)
11-15	32 (26%)
16-20	32 (26%)
21-25	13 (10%)
26+	14 (11%)

Abbreviations: ASA, American Society of Anesthesiologists; MIRP, minimally invasive radical prostatectomy; PSA, prostate-specific antigen.
* Among patients who underwent lymph node dissection.

Erectile and urinary functional outcomes reported 12 months postoperatively are presented in Supplemental Table 3. The 12 men who underwent a procedural intervention to control hemorrhaging had the lowest median erectile function scores, none of whom met the threshold for potency with an IIEF ≥22. By comparison, 17% of men who were serially monitored and 30% of men who received blood transfusion achieved IIEF ≥22 1-year postoperatively. Median urinary function scores were similar among the 3 groups as were the proportions achieving continence (urinary domain score of ≥17). As a benchmark comparison, in men without hemorrhage with available functional outcomes, 30% achieved IIEF ≥22 and 70% achieved continence 1-year postoperative.

DISCUSSION

In this study, we provide a comprehensive description of the clinical management and postoperative outcomes of men who experience clinically significant hemorrhage after MIRP. Clinically significant hemorrhage, as defined by our study group, is relatively uncommon and occurs in only 4% of all patients. Most of these patients stabilize without requiring transfusion or intervention. Irrespective of management strategy, all patients on this spectrum are more likely to utilize healthcare resources and experience complications than those without hemorrhage. This is true whether patients were observed, transfused, or if surgical intervention was required.

We chose to present our data using 3 clinical management groups: (1) patients who were serially monitored, (2) patients who received blood transfusion, and (3) patients who underwent a secondary procedural intervention to control hemorrhaging. While these groups reflect increasing severity of the same underlying problem, they are also relevant to clinical practice. Most men in our cohort (60%) were observed, likely reflecting that bleeding is mainly venous in nature and is often self-limited as the pelvic hematoma compresses the source of the bleeding.[13] Our overall transfusion rate of 1.6% was consistent with the published literature. While our study included some laparoscopic cases, the mean transfusion rate in a recent systematic review of robotic-assisted radical prostatectomy was comparable at 2%.[2]

Abdominopelvic imaging to localize bleeding was performed infrequently in the observation group relative to the transfusion and procedural intervention groups. CT angiography was only performed in 3 of the 25 patients who were imaged. Almost invariably, imaging studies demonstrated a pelvic hematoma, with or without hemoperitoneum. Active intravenous contrast extravasation was only documented in 1 case. This patient went on to have angioembolization of 2 branches of his internal iliac artery. Multiple reports of angioembolization after radical prostatectomy have been published.[7-9] A theoretical advantage of angioembolization over surgical exploration may be faster convalescence, although this procedure requires the expertise and availability of interventional radiology. Radiologic imaging clearly influenced management in this single case, but it may be largely noncontributory in most patients.

Table 2. Postoperative hemoglobin descriptions categorized by clinical management of postoperative hemorrhage.

	Serial Monitoring ($N = 91$; 60%)	Transfusion ($N = 48$; 32%)	Procedural Intervention for Hemorrhage (N = 12; 7.9%)
Median postoperative 4 or 14-h hemoglobin (g/dL)	11.0	9.5	8.8
Minimum postoperative 4 or 14-h hemoglobin (g/dL)	7.0	7.1	6.9
Maximum absolute decrease in hemoglobin (g/dL)*	6.4	7.8	7.8
Maximum relative decrease in hemoglobin*	45%	49%	53%

* Maximum decreases of preoperative to 4-h postoperative hemoglobin, preoperative to 14-h postoperative hemoglobin, to 4-h postoperative to 14-h postoperative hemoglobin.

Table 3. Description of secondary procedural interventions for the control of hemorrhage. Data presented as frequency.

Intervention	Intervention Year (Frequency)	Findings
Exploratory laparotomy ($n = 8$)	2010 (2)	Evacuation of clot only with no source identified ($n = 6$)*
	2012 (1)	Freely bleeding accessory pudendal artery ($n = 1$)
	2013 (1)	Bleeding from dorsal venous complex ($n = 1$)
	2014 (3)	
Exploratory laparoscopy ($n = 2$)	2013 (1)	Evacuation of clot only with no source identified ($n = 1$)
	2014 (1)	Bleeding from left neurovascular bundle ($n = 1$)
Robotic exploration ($n = 1$)	2015 (1)	Bleeding artery right obturator fossa
Angioembolization ($n = 1$)	2017 (1)	Coiled 2 actively bleeding branches of internal iliac artery

* One patient also underwent concurrent diverting ostomy for initially unrecognized colonic injury.

Table 4. Healthcare utilization outcomes categorized by clinical management of postoperative hemorrhage. Data presented as proportion (95% CI) and median (IQR).

	Serial Monitoring ($N = 91$; 60%)	Transfusion ($N = 48$; 32%)	Procedural Intervention for Hemorrhage ($N = 12$; 7.9%)
Emergency room visit within 30 d	23% (15%-33%)	25% (14%-40%)	58% (28%-85%)
Hospital readmission within 30 d	13.2% (7.0%-22%)	50% (35%-65%)	92% (62%, 100%)
Major (Grade III-V) complication within 30 d	6.6% (2.5%-14%)	19% (8.9%-33%)	100%*
Composite within 30 d (emergency room visit, or hospital readmission, or repeat surgical intervention, or major complication)	25% (17%-35%)	65% (49%-78%)	100%[a]
Maximum complication grade[†]			
2	6 (50%)	39 (81%)	0 (0%)
3	6 (50%)	7 (15%)	12 (100%)
4	0 (0%)	2 (4.2%)	0 (0%)
Length of stay (d)[‡]	1 (0-1)	3 (3-5)	4 (3-7)

Abbreviation: CI, confidence interval; IQR, interquartile range.
* 100% by definition.
[†] Among patients who had Grade II-V complications within 30 days of minimally invasive radical prostatectomy.
[‡] Includes 28 patients who underwent a procedural intervention (surgical or radiologic) within 30 d of minimally invasive radical prostatectomy (7 in the serial monitoring group, 9 in the transfusion group, and all 12 patients who underwent procedural intervention to control hemorrhage).

The decision to surgically explore 11 men was made clinically, based on hemodynamic instability without radiologic imaging. Given the low-event frequency it is difficult to reach firm conclusions regarding best practice in these situations. All surgical interventions occurred on the day of surgery or postoperative day 1. In the contemporary era, surgeons may favor a minimally invasive take-back given preoperative patient expectations. Case reports on the success of minimally invasive exploration in this setting are conflicted, citing challenges with establishing working space and evacuating blood with laparoscopic instruments.[5,6] Gong et al described their early experience with laparoscopic exploration, which was required in 3 of 910 laparoscopic cases.[14] They showed laparoscopy to be efficacious, while acknowledging the technical difficulty of this technique in the presence of large hematomas. In each case, the bleeding was secured after a thorough clot evacuation with either suture ligation, hemostatic agents, or both.[14] During 7 of our 11 explorations, no source of bleeding was identified after the clot was evacuated. This mirrors

the early experience of Bhayani et al, who found early (<10 hours) exploration for hemodynamic instability following laparoscopic renal surgery was more likely to identify discrete arterial bleeding, whereas later exploration was less likely to identify an active bleeding source.[15]

In historical reports of reoperation after ORP, the anastomosis was often taken down and reperformed to evacuate the hematoma and adequately control bleeding from the neurovascular bundles.[13] This was not required in our series, with active bleeding adequately controlled without the need for disturbing the urethrovesical anastomosis. Neither intervention approach nor finding of active bleeding at exploration had any bearing on composite 30-day complications or on 12-month functional recovery, though our study was not powered to demonstrate the significance of such impacts. While the choice of intervention approach was based on surgeon preference, it is notable that open exploration was more commonly performed earlier in our experience. All exploratory laparotomies were performed between 2010 and 2014. Laparoscopic and robotic exploration were less common, but the use of these techniques in later years likely represents increased surgeon experience and comfort using minimally invasive approaches.

Throughout the study period, it was our institutional practice to perform pelvic lymph node dissection on all patients with 2% or greater predicted probability of nodal metastases based on preradical prostatectomy nomogram, a practice currently recommended by the National Comprehensive Cancer Network.[16,17] Among all MIRP patients, 87% of men underwent pelvic lymph node dissection. The median number of nodes recovered during standard lymph node dissection was 11 (IQR 8, 16), compared to 16 (IQR 11, 22) during extended node dissection. We found no evidence of association between the number of nodes removed and concern for hemorrhage. The median number of nodes removed was 14 (IQR 10, 20) for men without concern for bleeding and 15 (IQR 10, 20) for those evaluated for postoperative hemorrhage (Wilcoxon rank-sum test P value = .6).

Nerve sparing was pursued aggressively when clinically indicated, regardless of preoperative erectile function. Nonthermal techniques that avoid traction to the neurovascular bundles were used exclusively. We did not find any evidence of association between nerve sparing and clinically significant hemorrhage or transfusion (P >.9). The DVC was ligated without use of clips and the decision to ligate the DVC before or after urethral transection varied by surgeon. During the study period, it became common institutional practice to ligate the DVC after urethral transection. Closed suction drains were used at surgeon's discretion, though their use was not routine or common during the study period. Fellows participated in most surgeries, with their role variable depending upon experience. Aspirin use was allowed throughout the perioperative period; anticoagulant or antiplatelet agents were stopped prior to surgery, if possible. Thirty-two (21%) men who met our laboratory threshold for hemorrhage remained on low-dose aspirin, 2 of whom required operative intervention. Four men who met our criteria for clinically significant hemorrhage continued anticoagulation. One of these men required surgical intervention. Among men who did not meet our clinical criteria for hemorrhage, there were similar rates of aspirin (26%) and anticoagulation (1.3%) use.

The overall major (grade ≥3) complication rate for all men undergoing MIRP over the study period was 4%. In our cohort, the serially monitored group had a similar high-grade complication rate of 6.5%, while the transfusion group had a significantly higher rate of 19%. Urinary leaks were documented in 16 of the 151 patients, a rate much higher than observed in our overall institutional experience (11% vs 2%). This is likely secondary to anastomotic distraction from the expanding pelvic hematoma. Accordingly, many of the high-grade complications involved percutaneous drainage of infected pelvic hematomas or abscesses. All leaks were managed conservatively and did not affect urinary control at 12 months.

Seventy percent of respondents achieved continence and 20% achieved potency by 1 year. We did not see evidence that functional outcomes for our 151-patient cohort differed importantly from our overall institutional data over the same period, especially since age and comorbidity are associated with both surgical complications and poor functional recovery. This may be reassuring to patients during counselling in the event of a bleeding complication. While numbers and response rates were limited in the procedural intervention group, none of these patients were potent at 12 months (IIEF-6 score ≥22), potentially reflecting the difficult nature of their initial prostatectomy or the sequelae of secondary intervention to control bleeding.

Some surgeons may take issue with our definition of a "clinically significant hemorrhage" for being too inclusive. Many factors, including patient BMI, volume status, intraoperative fluid administration, use of fluid bolus, and time of blood draw have been associated with decreased Hgb values postoperatively and there is no consensus definition of clinically significant hemorrhage based on Hgb values alone in the literature.[19] Our institution uses a hemoglobin decrease of ≥4 g/dL or 30% as a screening metric in the overall clinical evaluation for postoperative bleeding. Our overall definition was met in 4% of 3749 MIRPs performed over the 7-year study period, which is consistent with rates of clinical suspicion for postoperative bleeding. The 91 men who were serially monitored without transfusion had a 1-day median length of stay, but they also went to the ER and were readmitted to the hospital at rates that doubled our baseline MIRP experience (23% vs 10%; 13% vs 6%, respectively). Finally, while some men in the transfusion or secondary intervention groups did not satisfy our hemoglobin drop criteria, these men were treated expeditiously based on hemodynamic instability and other clinical parameters.

Our study has several limitations as a retrospective single high-volume cancer center review. While this study was retrospective, data were abstracted from a prospectively maintained surgical database and strengthened by

subsequent manual review. Complications data were extracted from the Memorial Sloan Kettering Cancer Center Surgical Secondary Events system. Regularly, this system is externally audited for quality and is especially robust for high-grade complications.[18] Initially, we sought to evaluate whether surgical exploration reduced the rate of complications or improved functional outcomes. Although historically recommended, the evacuation of pelvic hematomas to reduce complications is not grounded in evidence.[20] Even with a multiyear inclusion period at a high-volume tertiary care center, our numbers were too low in this group to permit any meaningful statistical comparisons. The decision to explore was made less than twice a year despite the performance of about 550 MIRPs annually. While it has been suggested that men with large pelvic hematomas may be at an increased risk for urinary extravasation and resultant vesicourethral anastomotic stenosis,[13] we were unable to clarify if intervention is beneficial in mitigating these complications.

CONCLUSION

Clinically significant postoperative hemorrhage is uncommon in the contemporary era of MIRP. The probability of an ER visit, hospital readmission or major complication for patients who experience even milder bleeding events was about twice the overall rate for all men undergoing MIRP at our institution who did not experience postoperative hemorrhage. Men who underwent secondary procedure to control bleeding appear to have poorer erectile functional outcomes 1 year postoperatively. The increase in risk is moderate, but still of sufficient size to warrant changes to patient counseling and postdischarge monitoring.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2019.04.021.

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