Notable Outcomes and Trackable Events after Surgery: Evaluating an Uncomplicated Recovery after Radical Prostatectomy

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Purpose: A priority of MUSIC (Michigan Urological Surgery Improvement Collaborative) is to improve patient outcomes after radical prostatectomy. As part of these efforts we developed a novel system that uses unambiguous events to define an uncomplicated 30-day postoperative recovery and compares these outcomes across diverse urology practices.

Materials and Methods: MUSIC used a consensus approach to develop an uncomplicated recovery pathway comprising a set of precise perioperative events that are reliably measured and collectively reflect resource utilization, technical complications and coordination of care. Events that occurred outside the uncomplicated recovery pathway were considered deviations, including rectal injury, high blood loss, extended length of stay, prolonged drain or catheter placement, catheter replacement, hospital readmission or mortality. For men undergoing radical prostatectomy trained abstractors prospectively recorded clinical and perioperative data in an electronic registry. When a deviation from the NOTES (Notable Outcomes and Trackable Events after Surgery) pathway occurred, precipitating events were described by abstractors and we analyzed the events.

Results: From April 2014 through July 2015 a total of 2,245 radical prostatectomies were performed by 100 surgeons in a total of 37 diverse participating MUSIC practices. In the 29 practices in which 10 or more radical prostatectomies were performed during the interval analyzed the risk adjusted deviation rate ranged from 0.0% to 46.1% ($p < 0.0001$). Anastomotic and gastrointestinal events were contributing factors in 50.2% of deviated cases.

Conclusions: The novel NOTES system provides comparative data on unambiguous and actionable short-term outcomes after radical prostatectomy. The observed variation in outcomes across practices suggests opportunities for quality improvement initiatives. Decreasing anastomotic and gastrointestinal events represents a high impact opportunity for initial quality improvement efforts.

Key Words: prostate, prostatectomy, outcome assessment (health care), quality improvement, data collection

Abbreviations and Acronyms

BMI = body mass index
EBL = estimated blood loss
GI = gastrointestinal
LOS = length of stay
PSA = prostate specific antigen
RP = radical prostatectomy

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In the United States there has been a significant shift toward measuring the value of health care provided to patients, which is typically measured by tracking the quality and the cost of care.[1] Surgical complications increase

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the cost and decrease the quality of care. Therefore, they are logical targets for initiatives aimed at enhancing the value of surgical care. Prior analyses of population based data showed a 21.9% complication rate for RP, one of the most common oncologic procedures performed by urologists.[2] While reducing complications makes great sense, the ability of clinicians to identify opportunities for improvement and measure the success of subsequent interventions requires access to pragmatic and trustworthy data on the frequency of specific perioperative events.

Traditional data sources to track perioperative complications after RP lack reliability and are often difficult to translate into meaningful quality improvement activities. Administrative claims data do not include robust, specific clinical information and are subject to the interpretation of medical billing coders.[3] Standard chart review data have several limitations, including disparities in clinician and abstractor interpretations of complication definitions and reporting of generic surgical complications that are difficult to categorize for actionable change.[4] The Clavien-Dindo system has improved the reporting of complications across a wide breadth of surgical procedures. However, certain events such as urine leak after RP may still be reported variably due to inconsistencies in categorizing the events as complications vs sequelae. Furthermore, the Clavien-Dindo system may not offer insights into aspects of care that are important to patients but may not represent a traditional complication, such as prolonged catheter placement. An ideal perioperative outcomes tracking system would provide consistent, objective and procedure specific measures that are pertinent and actionable for surgeons pursuing quality improvement as well as meaningful to patients.[5]

In this context we developed a system to assess short-term recovery after RP that provides more reliable, meaningful and actionable data. Additionally, we developed a statewide reporting system to provide clinicians with access to their outcomes data compared to that of their peers. We hypothesized that our novel measure, NOTES, would identify variances in recovery after RP that clinicians can translate into specific quality improvement initiatives aimed at making early recovery easier for men undergoing RP.

METHODS

Michigan Urological Surgery Improvement Collaborative

MUSIC (www.musicurology.com) was established in 2011 as a physician led, quality improvement consortium. The primary goal of the collaborative is to improve the quality and cost efficiency of care provided to men with prostate cancer in Michigan. Currently 42 community based and academic practices participate in the collaborative, representing approximately 85% of urologists in Michigan. Due to the MUSIC focus on quality improvement each practice was able to obtain regulatory exemption from local internal review boards prior to participating.

NOTES Metric Development

MUSIC quality improvement efforts are guided by topic specific working groups comprising expert urologists and patient advocates from across the consortium. Members of the RP working group used a consensus approach to identify data points that should be tracked to measure perioperative outcomes. They aimed to select measures that were reliable, meaningful and actionable. The RP working group also followed the principles that data points must be unambiguous and easy to extract from medical records, and the measures must collectively reflect practice patterns, coordination of care, technical complications and resource utilization.

The RP working group reached consensus. They identified 4 distinct phases of perioperative care and 2 data points to evaluate each phase, including rectal injury and EBL to measure the intraoperative phase, LOS and duration of drain use to assess the hospitalization phase, catheter duration and catheter replacement reflecting postoperative catheter management and finally hospital readmission and mortality as indicators of 30-day postoperative outcomes.

Following development by the RP working group, including endorsement by patient advocates, threshold criteria were established to set maximum limits for each data point. Therefore, the NOTES uncomplicated RP recovery pathway was collectively defined as 1) no rectal injury, 2) EBL 400 ml or less for laparoscopic approaches, or 1,300 ml or less for open or perineal approaches, 3) LOS 2 days or less, 4) drain placement 2 days or less, 5) catheter placement 16 days or less, 6) no 30-day indwelling catheter replacement, 7) no 30-day hospital readmission and 8) no 30-day mortality. Perioperative events occurring outside any criteria, such as readmission or 4-day LOS, were considered deviations from the uncomplicated recovery pathway.

Data Collection

Trained data abstractors at each site prospectively enter standardized clinical, pathological and perioperative morbidity data elements into an electronic clinical registry for patients treated with primary or salvage RP. Programming in the registry software automates calculations for days of LOS, drain placement and catheter placement based on surgery, discharge home, drain removal and catheter removal dates entered by data abstractors. After a deviation from the uncomplicated pathway criteria is identified by the registry, data abstractors are asked to answer supplemental questions describing the underlying events associated with that deviation. We reviewed these underlying events, termed deviation drivers, and assigned them to categories to analyze trends in the types of events that caused deviations.

Provider Feedback

Personally tailored, data driven provider feedback reports are automatically generated into PDFs and disseminated from the MUSIC Coordinating Center using SAS® Output Delivery System techniques. MUSIC urologists may receive feedback reports through an automated electronic system or at a physical address.

The report was developed using structured evaluation comments provided by pilot participants about design, clarity, statistical methodology and delivery processes. Reports include a table highlighting comparative surgeon, practice and collaborative level performances across each of the 8 NOTES criteria. Overall rates of cases experiencing at least 1 deviation are also presented. Trend graphs offer analyses of progress with time. Case level details and deviation driver data are also provided to further facilitate the development of targeted local quality improvement interventions. The supplementary Appendix (http://jurology.com/) shows an example of a report.

Statistical Analyses

The primary cohort for this analysis was men undergoing RP in MUSIC practices from April 2014 through July 2015. To account for case mix variations among practices we fitted a multivariable logistic regression model with 95% CIs to estimate collaborative and practice level deviation rates from the NOTES uncomplicated pathway. Risk adjustment variables included patient characteristics of age, race, insurance status, Charlson comorbidity index, BMI, PSA, prostate volume, pathological Gleason score and pathological T stage. The chi-square test was used to test for significant differences between practice level rates of deviation. All analyses were performed at the 5% significance level using SAS 9.3.

RESULTS

From April 2014 through July 2015 a total of 2,245 RPs were performed by 100 surgeons in a total of 37 participating MUSIC practices. Of these cases 2,202 (98.1%) were primary treatment RP. Of the RPs 95.9% were performed by a robotic or laparoscopic approach. Open and perineal RP approaches were used in 4.1% of cases.

At the patient level 20.6% of men experienced at least 1 deviation from the NOTES uncomplicated recovery pathway, including 13.1% of men with 1 deviation, 5.4% with 2 deviations and 2.1% with 3 or more deviations. Black men, and men with public insurance, higher PSA, BMI 30 kg/m^2 or greater, higher Charlson comorbidity index, pathological Gleason score 8 or greater (each $p < 0.01$) or pathological stage T2c or greater ($p = 0.01$) were more likely to show deviation from the NOTES uncomplicated recovery pathway than their counterparts (table 1).

The risk adjusted case deviation rate for the entire collaborative was 19.8% (95% CI 18.9–21.6). In the 29 practices in which at least 10 RPs were

Table 1. *Demographic and clinical characteristics of men with and without NOTES deviations*

	NOTES Deviation				
	No		Yes		p Value
No. pts	1,782		463		—
Median age (range)	63	(36–83)	63	(44–100)	0.4048 (Wilcoxon rank sum test)
Median ng/ml PSA (range)	5.7	(0.09–85.7)	6.2	(0.09–124.6)	0.0021 (Wilcoxon rank sum test)
No. race (%):					<0.0001 (chi-square test)
White	1,435	(85.4)	333	(76.9)	
Black	178	(10.6)	90	(20.8)	
Other	67	(4.0)	10	(2.3)	
No. primary insurance (%):					0.0092 (chi-square test)
Private	1,187	(66.9)	281	(60.8)	
Public	578	(32.6)	181	(39.2)	
Uninsured/self-pay	10	(0.6)	0		
No. kg/m^2 BMI (%):					0.0006 (chi-square test)
Less than 25	306	(18.1)	94	(21.4)	
25–29	799	(47.1)	162	(36.9)	
30 or Greater	590	(34.8)	183	(41.7)	
No. Charlson comorbidity index (%):					0.0014 (chi-square test)
0	1,321	(74.2)	306	(66.1)	
1	295	(16.6)	94	(20.3)	
2+	165	(9.3)	63	(13.6)	
No. Gleason score (%):					0.0004 (chi-square test)
6 or Less	325	(18.6)	61	(13.3)	
7	1,236	(70.7)	322	(70.3)	
8–10	187	(10.7)	75	(16.4)	
No. pathological T stage (%):					0.0141 (chi-square test)
T2c or less	1,267	(71.1)	302	(65.2)	
Greater than T2c	515	(28.9)	161	(34.8)	
No. cc prostate vol (%):					0.0697 (chi-square test)
Less than 29	385	(32.5)	113	(35.0)	
29–42	414	(34.9)	91	(28.2)	
Greater than 42	386	(32.6)	119	(36.8)	

performed during the interval analyzed the risk adjusted deviation rate ranged from 0.0% to 46.1% ($p < 0.001$). For the highest rate practice the 95% CI was 34.0–53.7 while the 95% CI for the lowest rate practice was not available because the deviation rate was 0% (fig. 1). Of the individual NOTES measures deviations in drain placement in 8.3% of cases, LOS in 8.2% and catheter placement in 4.8% were the most common deviations. Rectal injury and mortality occurred rarely in 0.4% and 0.2% of cases, respectively (fig. 2).

When examining NOTES deviation events, urine leaks in 31.4% cases and GI causes such as ileus and bowel injury in 23.2% were the most frequent contributors to deviations. Table 2 shows the proportion of each deviation related to GI events and/or urine leaks for postoperative deviation events. Urine leaks contributed to 10.9% of LOS deviations, 52.7% of drain deviations, 38.9% of catheter duration deviations and 17.4% of readmissions. Gastrointestinal causes contributed to 34.2% of LOS deviations, 38.0% of readmissions and 20.0% of 30-day mortalities. Collectively, urine leaks and GI causes contributed to 50.2% of deviated cases.

Concise, confidential physician level reports with risk adjusted and actionable feedback were distributed to all 100 MUSIC providers currently performing RP. Although an opt out system was offered, all 100 surgeons chose to continue receiving NOTES reports and all 100 providers preferred electronic dissemination of reports. At the MUSIC coordinating center 2 cycles of quarterly, risk adjusted NOTES reports have been generated and disseminated to all providers. Using the automated reporting system each statewide cycle of generating and disseminating provider level reports required less than 15 minutes of processing time.

DISCUSSION

MUSIC has been able to successfully develop and implement a novel system to assess uncomplicated recovery after RP. NOTES uses dependable data collection of perioperative events that can be returned to urologists for local quality improvement interventions. Each data point in the NOTES pathway is an objective, unambiguous measure that is not subject to abstractor or physician interpretation of patient intraoperative and postoperative courses.

Baseline analyses of deviations from the NOTES uncomplicated RP recovery pathway suggest that there is wide variation across the state in the occurrence of these adverse events. This variation, ranging from 0.0% to 46.1% of cases, highlights the importance of focused and local quality improvement efforts. Urine leaks and gastrointestinal events collectively contributed to approximately half of the cases experiencing deviation from the NOTES uncomplicated recovery pathway. They represent specific, high impact opportunities for initial quality improvement efforts.

The NOTES process is consistent with existing literature describing essential elements of perioperative complication measurement, including standardization of definitions across diverse settings, reduced subjectivity, provision of robust clinical information, procedure specific metrics and assessment of actionable processes of care.[3–6] NOTES expands this body of work using objective and consistently available data points to optimize the

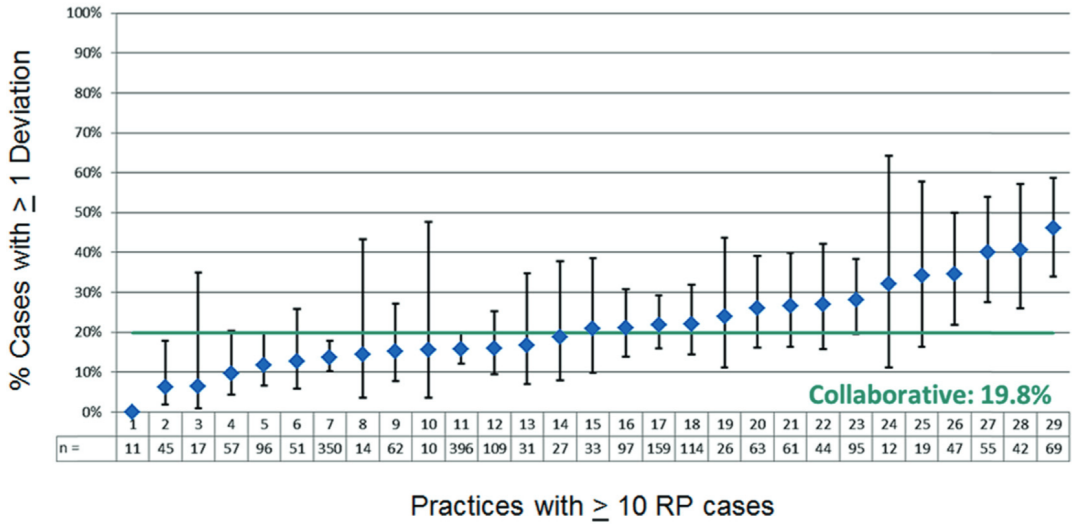

Figure 1. Variation in NOTES deviation rate across MUSIC practices in all RP cases included in analysis at each practice. Of 29 practices performing at least 10 RP cases from April 2014 through July 2015 rate ranged from 0.0% to 46.1% ($p < 0.001$). This wide variation suggests opportunities for quality improvement.

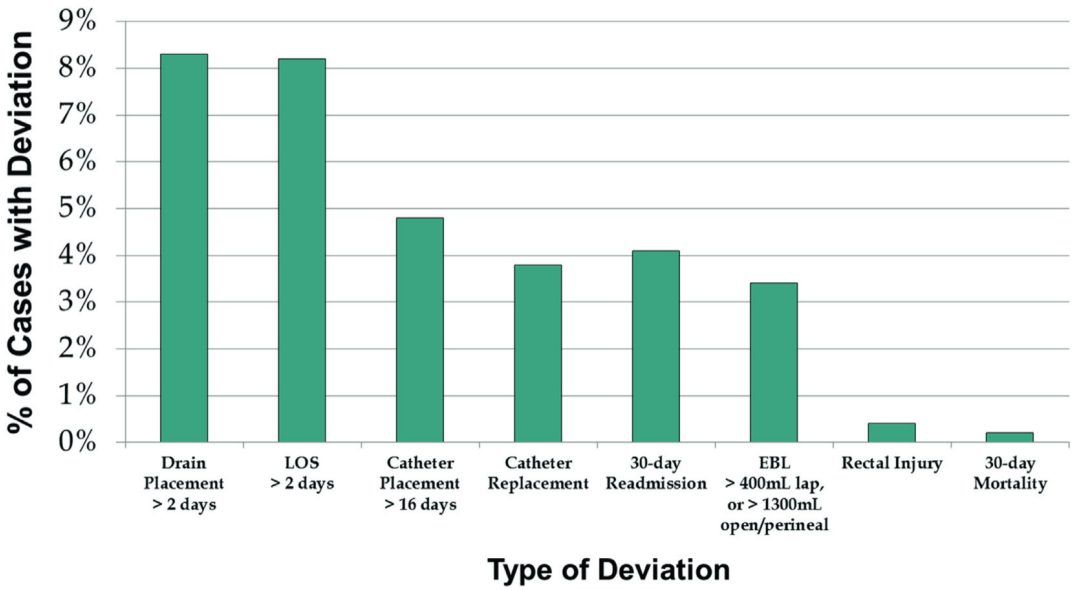

Figure 2. Drain placement and LOS were most frequent NOTES deviation types. Rectal injury and 30-day mortality were uncommon. *lap,* laparoscopic.

dependability of reported data. NOTES can be a useful adjunct to the Clavien-Dindo system by leveraging data points that are procedure specific and meaningful from the patient perspective. Additionally, NOTES promotes continuation of the quality improvement process by providing urologists with direct feedback reports that inform and motivate local physician led quality improvement efforts.

There are several potential limitations to our findings warranting consideration. 1) Our results are restricted to practices participating in the MUSIC collaborative, which have varying annual RP case volumes. Nonetheless, the fundamental principles of NOTES data collection and reporting are designed to support reliability across diverse practice settings. 2) NOTES focuses on 30-day recovery outcomes and does not account for important long-term outcomes such as cancer control or urinary and sexual function. However, using NOTES to improve perioperative outcomes does not preclude also evaluating these long-term outcomes. 3) Our tool does not track all possible adverse events so that minor complications that do not cause deviations from the uncomplicated recovery pathway may not be captured. 4) The precise threshold for each criterion may require future modifications to provide optimal perioperative assessments and identification of quality improvement opportunities. These ongoing revisions are planned as NOTES generates quality improvement interventions that elevate standards of care.

Table 2. *Most frequent underlying causes of postoperative NOTES deviation events*

Deviation Event	No. Pts	No. Deviation Cause (%)*	
		Gastrointestinal	Urine Leak
LOS greater than 2 days	184	63 (34.2)	20 (10.9)
Duration (days):			
Drain (greater than 2)	186	3 (1.6)	98 (52.7)
Catheter (greater than 16)	108	8 (7.4)	42 (38.9)
30-Day:			
Readmission	92	35 (38.0)	16 (17.4)
Mortality	5	1 (20.0)	0

*Catheter replacement deviations excluded since data collection on catheter replacement deviation causes began after analysis.

These limitations notwithstanding, our results have significant implications for clinical stakeholders and policymakers. Clinicians benefit from having a perioperative outcomes tracking system such as NOTES that offers unequivocal, comparative and objective performance feedback. The NOTES system provides surgeons with reliable data that can be used to motivate quality improvement and decrease practice level variation. Importantly, patients ultimately will benefit through easier recovery experiences and improved care delivered across diverse sites.

Our findings are also relevant to policy makers. NOTES enables leaders seeking to improve the value of surgical care to reliably track meaningful perioperative outcomes across a diverse array of health care settings. NOTES outcomes are easily translated into specific, data driven quality improvement targets, which will increase the likelihood of successfully reducing costly complications and improving the value of care.

CONCLUSIONS

NOTES delivers reliable, meaningful and actionable perioperative outcomes data across diverse practice settings. There is wide variation in NOTES deviations across MUSIC practices, which highlights the importance of quality improvement tools such as NOTES. We have observed the feasibility of using NOTES to identify explicit, high impact quality improvement targets. The next steps include further validating NOTES outcomes by investigating correlations with cancer control, patient reported outcomes, video review of surgical techniques and episode costs. Ultimately, better measurement of perioperative outcomes and understanding of underlying mechanisms driving adverse recovery events will yield more successful quality improvement strategies benefiting providers and patients.

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