Simple frameshifts in minimally invasive surgery postoperative pain management significantly reduce opiate prescriptions

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Introduction: *To evaluate the impact of an "opt-in" non-narcotic postoperative pain regimen on narcotic utilization and patient-reported pain scores.*
Materials and methods: *A prospective, non-blinded pre- and post-interventional trial was conducted, including a lead-in period for baseline evaluation. The intervention group received a new pain protocol prioritizing non-narcotic medications, an "opt-in" requirement for opiates, and standardized patient education. Study outcomes included opiate prescription and utilization (measured in Morphine Equivalent Doses) and reported pain scores on postoperative day (POD) 1, discharge and follow up.*
Results: *At discharge, 70% fewer patients were prescribed any opioids (ARR: -0.7; p < 0.001); the amount prescribed was reduced by 95% (pre-intervention 69.3 mg versus post-intervention 3.5 mg, p < 0.001). Mean opioids used following discharge decreased by 76% (14.7 mg versus 3.5 mg, p = 0.011). In a subgroup analysis of robotic prostatectomies, there was a 95% reduction in mean opioids prescribed at discharge (64.6 mg versus 3.2 mg, p < 0.001) and 82% reduction in utilization over entire postoperative course (87.6 mg versus 15.7 mg, p = 0.001). There was no significant difference in pain scores between intervention groups at POD 1, discharge and follow up for patients (entire cohort and post-prostatectomy).*
Conclusion: *A standardized pain protocol with "opt-in" requirements for opiate prescription, emphasis on non-narcotic medications, and patient education, resulted in significant reductions in opioid use. Simple frameshifts in pain management can yield significant gains in the opioid epidemic.*

Key Words: narcotics, pain postoperative, minimally invasive surgical procedures, urology

Introduction

The U.S. opioid crisis has risen to the forefront of the medical community's consciousness, partly due to the sharp rise in opioid use and abuse over the past two decades.[1] Many patients first encounter opioids as part of standard postoperative pain management.[2,3] Indeed, 1 in 16 surgical patients prescribed narcotics become long term users, and 6% of opioid-naïve surgical patients become newly addicted.[2,3] Prescribing opioids to surgical patients is particularly complicated as clinicians must balance pain management against the risk of abuse.[4] As a result, there exists a significant variation in physician prescription patterns, and opioid-naïve and opioid-tolerant patients are at risk for misuse, abuse, addiction, overdose, and diversion that can accompany persistent opioid use.[4,5]

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Minimally invasive surgery (MIS) is increasingly popular with patients and practitioners, offering decreased postoperative morbidity, hospital stay, costs and pain while maintaining excellent surgical outcomes.[6] Despite these advantages, opioids are routinely prescribed to patients undergoing MIS. Knight et al found that similar amounts of opioids were prescribed following open inguinal hernia repairs and minimally invasive repairs, and that patients were not using significantly different amounts of opioids based on surgical approach.[7] Other studies of open and laparoscopic surgeries on a general surgery service found that less than one-third of opioids prescribed were being consumed.[8] When one study instituted a restrictive opioid prescribing protocol following gynecologic oncology surgery, there was a reduction in opioids prescribed in both the minimally invasive cohort and the laparotomy cohort, without an increase in refill requests or difference in pain scores.[9] Within the field of urology, one prospective study showed a median prescription of 27 oxycodone equivalents following both minimally-invasive nephrectomy and robotic-assisted laparoscopic prostatectomy, the majority of which went unused.[10,11] The PENN cohort study - one of the only prospective trials of a novel protocol to reduce opioid use after urologic surgery - found that two-thirds of patients undergoing MIS were able to be discharged without pain medications. They also found that there were no differences in pain score between those who received opioids at discharge and those who did not.[12] Thus, reducing the utilization of opiates after MIS appears to be a critical opportunity for mitigating the opioid epidemic without sacrificing adequate pain control.[7-13]

In an effort to address this, we assessed the impact of an "opt-in" postoperative pain protocol in an interventional study of urologic oncology patients undergoing MIS at Thomas Jefferson University Hospital, a tertiary care referral center in Philadelphia.

Materials and methods

Patients undergoing MIS on the urologic oncology service over a 2-month period were identified for this IRB- approved study. Patients with a history of chronic opioid use were excluded. All remaining eligible patients were recruited during a lead-in period (June 2019) as the pre-intervention (PrI) group, Figure 1. PrI participants received the established pain control regimen, with opioids automatically prescribed as part of an order set during the hospital course and at the time of discharge. During the second month (July 2019), all eligible patients were recruited to participate in the post-intervention, PoI, group, Figure 1. These patients were treated with a newly-designed pain protocol aimed at reducing narcotic prescriptions. Notably, this protocol required prescribers to "opt-in" for opioid orders based on their assessment of a patient's pain, rather than automatically ordering them to be used as needed. The protocol also emphasized the prescription of non-narcotic pain medications, such as NSAIDs or acetaminophen, as first-line therapy; opioids were then made available if patients continued to have pain after receiving first-line medications. Patients were

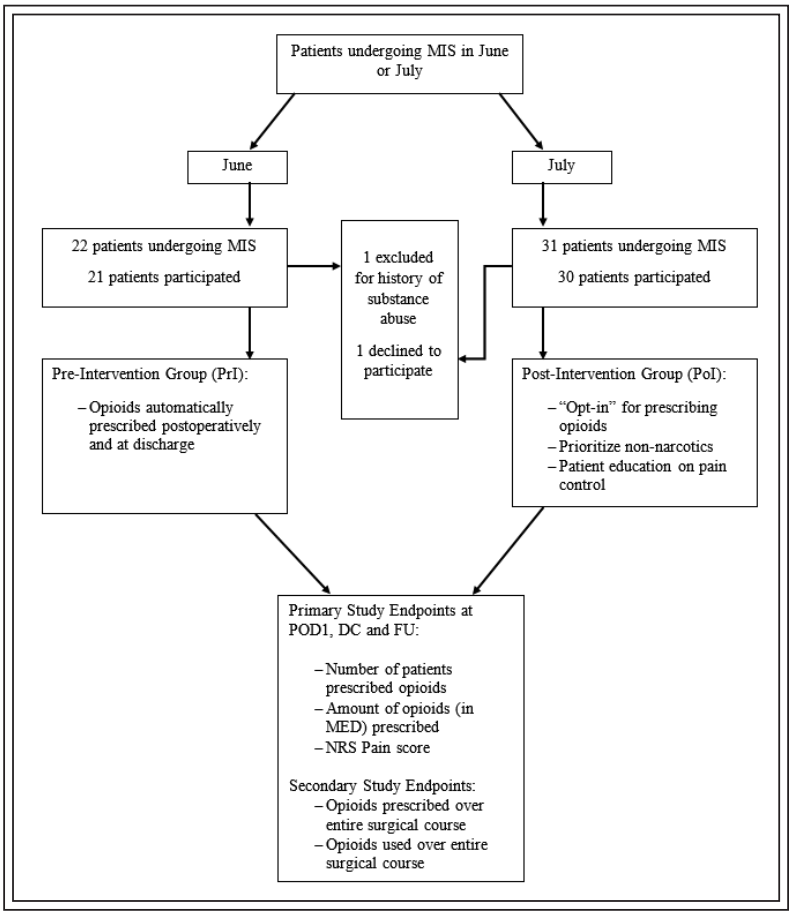
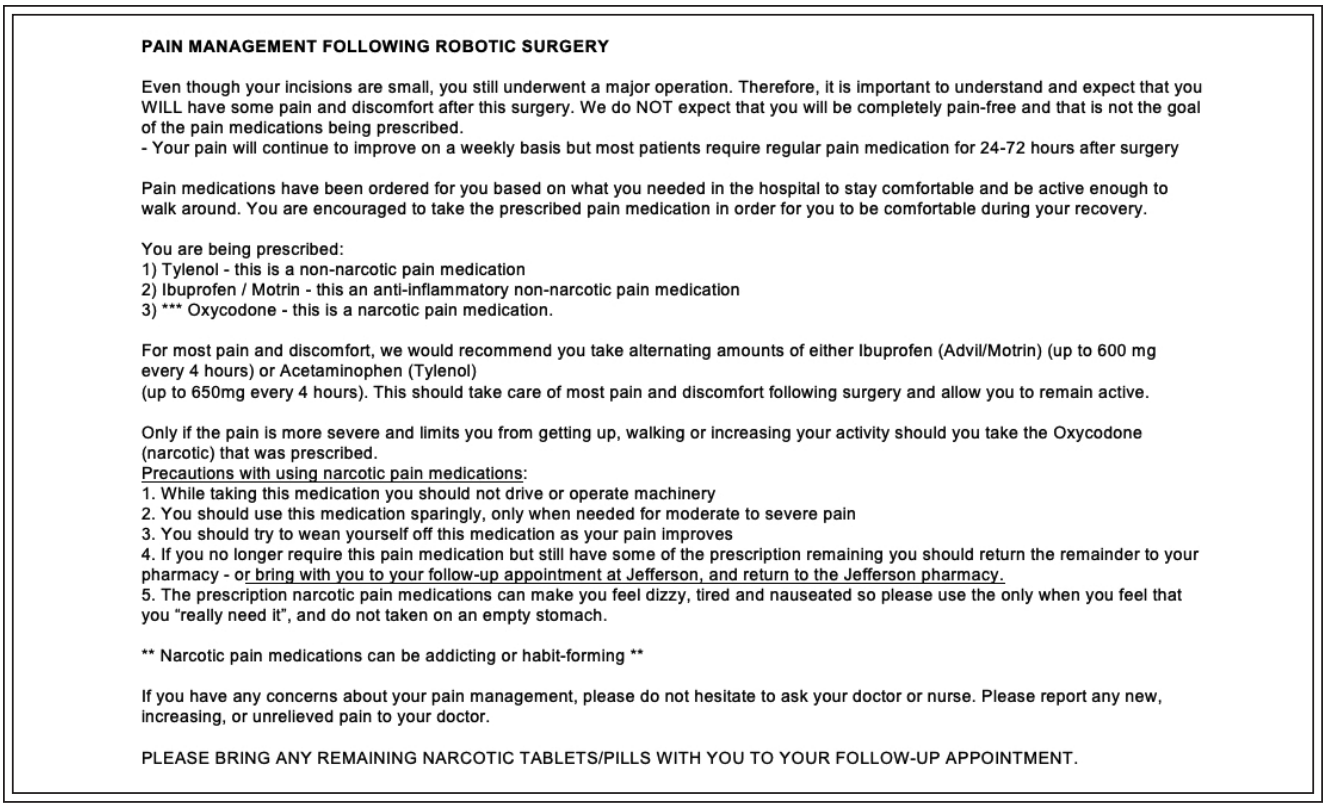


Figure 1. Study design and endpoints. Patients in the first month received the current pain protocol, with opioids automatically ordered. Patients in the second month received the novel pain protocol, which required providers to "opt in" to prescribing.



PAIN MANAGEMENT FOLLOWING ROBOTIC SURGERY

Even though your incisions are small, you still underwent a major operation. Therefore, it is important to understand and expect that you WILL have some pain and discomfort after this surgery. We do NOT expect that you will be completely pain-free and that is not the goal of the pain medications being prescribed.
- Your pain will continue to improve on a weekly basis but most patients require regular pain medication for 24-72 hours after surgery

Pain medications have been ordered for you based on what you needed in the hospital to stay comfortable and be active enough to walk around. You are encouraged to take the prescribed pain medication in order for you to be comfortable during your recovery.

You are being prescribed:
1) Tylenol - this is a non-narcotic pain medication
2) Ibuprofen / Motrin - this an anti-inflammatory non-narcotic pain medication
3) *** Oxycodone - this is a narcotic pain medication.

For most pain and discomfort, we would recommend you take alternating amounts of either Ibuprofen (Advil/Motrin) (up to 600 mg every 4 hours) or Acetaminophen (Tylenol)
(up to 650mg every 4 hours). This should take care of most pain and discomfort following surgery and allow you to remain active.

Only if the pain is more severe and limits you from getting up, walking or increasing your activity should you take the Oxycodone (narcotic) that was prescribed.
Precautions with using narcotic pain medications:
1. While taking this medication you should not drive or operate machinery
2. You should use this medication sparingly, only when needed for moderate to severe pain
3. You should try to wean yourself off this medication as your pain improves
4. If you no longer require this pain medication but still have some of the prescription remaining you should return the remainder to your pharmacy - or bring with you to your follow-up appointment at Jefferson, and return to the Jefferson pharmacy.
5. The prescription narcotic pain medications can make you feel dizzy, tired and nauseated so please use the only when you feel that you "really need it", and do not taken on an empty stomach.

** Narcotic pain medications can be addicting or habit-forming **

If you have any concerns about your pain management, please do not hesitate to ask your doctor or nurse. Please report any new, increasing, or unrelieved pain to your doctor.

PLEASE BRING ANY REMAINING NARCOTIC TABLETS/PILLS WITH YOU TO YOUR FOLLOW-UP APPOINTMENT.

Figure 2. SmartPhrase for postsurgical discharge instructions.

prescribed opiates at discharge only if they required opioids in the 24 hours prior to discharge, and were provided educational materials on pain management expectations in their discharge instructions, Figure 2. To evaluate the efficacy of this new protocol, primary endpoints included patient numerical rating scale (NRS) pain scores as well as opioid use at postoperative day 1 (POD1), discharge, and follow up. Secondary endpoints included prescription and usage of opiates over the entire surgical course for both groups. This was recorded in morphine equivalent doses (MED). Geometric means were calculated for MED at each time point. T-tests of logarithmic data were performed for MED comparisons (alpha- level: 0.05), and the Mann-Whitney test of significance for non-parametric data was used for NRS pain scores.[14] Data analyses were performed using SAS 9.4. We hypothesized there would be no difference in patient-reported pain at POD1, discharge or follow up between the two pain protocols.

Results

Demographics

Patient demographics are provided in Table 1. Surgeries for each intervention group were performed by the same five urologic oncologists. A total of 21 participants were recruited to the PrI group; one additional patient was excluded due to a history of opioid abuse. Thirty-one patients were approached to participate in the PoI group; 1 declined and 30 were recruited. The PrI group and PoI were demographically similar (mean age: 61.8 versus 59.9 years; percent of male patients: 86% versus 83%, respectively). Sixteen patients in the PrI group underwent robotic prostatectomies, 4 received robotic nephrectomies, and 1 underwent another MIS procedure. Of the patients in the PoI group, 21 underwent robotic prostatectomies, 6 received nephrectomies (1 laparoscopic and 5 robotic), and 3 underwent another type of MIS. The mean time to follow up in PrI was 11.9 days (range: 5-29 days, SD: 6.1 days) and 9.9 days in the PoI (range: 6-21 days, SD: 3.4 days). One patient in the PoI group was lost to follow up after discharge.

General cohort

The mean MED during the postoperative period in the PoI group was 16.9 mg compared to 15.2 mg in the PrI group ($p = 0.845$). At the time of discharge, there was a 70% reduction (ARR: -0.7, $p < 0.001$, 95% CI [-0.86 to -0.54]) in the number of patients prescribed any

TABLE 1. **Characteristics of intervention groups**

	Overall (n = 51)	Prl (n = 21)	Pol (n = 30)
Age, mean (SD)	60.7 (10.0)	61.8 (10.6)	59.9 (9.6)
EBL (mL, mean (SD))	266.2 (194.9)	254.8 (164.2)	274.2 (216.2)
LOS (days, mean (SD))	1.5 (1.1)	1.4 (0.9)	1.6 (1.3)
Interval from discharge to follow up (days, mean (SD))	10.7 (4.8)	11.9 (6.1)	9.9 (3.4)
Gender, n (%)			
Male	43 (84.3%)	18 (85.7%)	25 (83.3%)
Female	8 (15.7%)	3 (14.3%)	5 (16.7%)
Race, n (%)			
White/Caucasian	32 (62.8%)	10 (47.6%)	22 (73.3%)
Black/African American	14 (27.5%)	9 (42.9%)	5 (16.7%)
Hispanic	4 (7.8%)	2 (9.5%)	2 (6.7%)
Asian	1 (2.0%)	0 (0.0%)	1 (3.3%)
Primary condition, n (%)			
Prostate cancer	37 (72.5%)	16 (76.2%)	21 (70.0%)
Bladder cancer	2 (3.9%)	1 (4.8%)	1 (3.3%)
Others	12 (23.5%)	4 (19.0%)	8 (26.7%)
Surgery performed, n (%)			
Robotic prostatectomy	37 (72.5%)	16 (76.2%)	21 (70.0%)
Minimally invasive nephrectomy	10 (19.6%)	4 (19.0%)	6 (20.0%)
Others	4 (7.8%)	1 (4.8%)	3 (10.0%)

Prl = pre-intervention; PoI = post-intervention; SD = standard deviation; EBL = estimated blood loss; LOS = length of stay

opioids; in patients prescribed opioids, there was a 95% decrease in the amount prescribed between groups (PrI 69.3 mg versus PoI 3.5 mg, $p < 0.001$), Table 2. Two patients in the PrI group requested opioids after discharge, compared to three in the PoI group. There was a 76% reduction in mean MED used by patients in this period following discharge (PrI 14.7 mg versus PoI 3.5 mg, $p = 0.011$), Table 2. Total mean values of opioids prescribed (postoperative, discharge, and additional amounts requested by patients at home) and opioids used by patients were compared between the PrI and PoI groups, revealing a 77% reduction in MED prescribed ($p = 0.002$) and a 42% reduction in MED used ($p = 0.327$). The mean NRS pain score at POD1, discharge and follow up visit were 4.0, 3.6 and 1.5 in the PrI group, and 4.5, 4.1 and 1.6 in the PoI group, respectively. There was no significant difference in pain at each time point between groups, Table 2; Figure 3.

Robotic-assisted laparoscopic prostatectomy cohort

A subset analysis was performed on the 37 patients who underwent robotic prostatectomies (RALP), as this remains the most common MIS procedure within urologic oncology and of unique interest. In the PrI group, mean length of stay was 1 day (SD: 0 days), and 1.05 (SD: 0.22 days) in the PoI group ($p = 0.390$, 95%

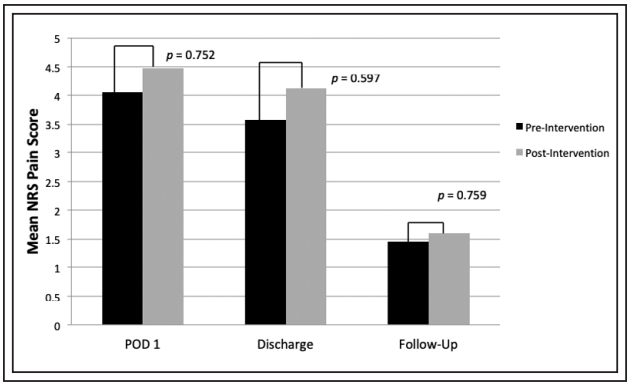


Figure 3. Mean NRS pain scores over the surgical course in the general cohort. There was no difference in NRS pain scores between the pre- and post-intervention groups at POD1, discharge or follow up.

TABLE 2. **Group mean MED and NRS**

	PrI (n = 21)	PoI (n = 30)	p value[a]
Postoperative			
Patients receiving narcotics, n (%)	15 (71.4%)	23 (76. 7%)	0.673
MED (mg, mean[b] [95% CI[b]])	15.2 [6.4, 36.1]	16.9 [8.5, 33.6]	0.845
MED (mg, median (Q1-Q3))	32.5 (0-56)	26.3 (7.5-67.5)	
NRS pain score, mean (SD), [95% CI]	4.0 (2.8), [2.8, 5.3]	4.5 (3.0), [3.3, 5.6]	0.752
Discharge			
Patients discharged on narcotics, n (%)	21 (100.0%)	9 (30.0%)	< 0.001
MED (mg, mean[b] [95% CI[b]])	69.3 [60.0, 80.2]	3.5 [1.7, 7.4]	< 0.001
MED (mg, median (Q1-Q3))	75 (60-75)	0 (0-37.5)	
NRS pain score, mean (SD), [95% CI]	3.6 (2.6), [2.4, 4.7]	4.1 (2.6) , [3.1, 5.1]	0.597
Follow up			
Patients receiving additional narcotics, n (%)	2 (9.5%)	3 (10.3%)	0.924
MED (mg, mean[b] [95% CI[b]])	14.7 [5.9, 36.7]	3.5 [1.7, 7.0]	0.011
MED (mg, median (Q1-Q3))	37.5 (0-60)	0 (0-30)	
NRS pain score, mean (SD), [95% CI]	1.5 (2.1), [0.5, 2.4]	1.6 (2.6) , [0.6, 2.6]	0.759
MED over entire surgical course			
Prescribed (mg, mean[b] [95% CI[b]])	103.0 [79.9, 132.7]	23.3 [10.9, 49.8]	0.002
Used (mg, mean[b] [95% CI[b]])	35.8 [15.1, 84.9]	20.9 [10.1, 43.1]	0.327

[a]p value corresponds to t-test of logged data for MED variables, Mann-Whitney test for continuous variables (NRS pain scores), and $\chi 2$ test for categorical variables
[b]geometric mean and its 95% confidence interval
MED = morphine equivalent doses; SD = standard deviation; CI = confidence interval; Q1 = lower quartile; Q3 = upper quartile; NRS = numerical rating scale

CI [-0.16 to -0.06]). Ten of 16 patients in the PrI group received opioids in the postoperative period, compared to 15 of 21 in the PoI group. Neither the number of patients receiving opioids nor the mean amount of opioids received during this period was significantly different between the two groups, Table 3; p = 0.565 and 0.792, respectively). However, at discharge, there was a significant difference in patients who were prescribed opioids: 100% of patients in the PrI group were discharged with opioids, compared to 29% in the PoI group (16 versus 6 patients, ARR: -0.71, p < 0.001, 95% CI [-0.91 to -0.52]). PrI patients also received significantly more opioids at discharge (64.6 mg PrI versus 3.2 mg PoI, p < 0.001). Two patients required additional opioids at the time of follow up, both of whom were in the PoI group (p = 0.288) and who received a mean MED of 1.5 mg (0 mg PrI versus 1.5 mg PoI, p = 0.163). For patients undergoing prostatectomy, we found that there was an 82% reduction in the amount of opioids prescribed over the entire surgical course between the PrI and PoI group (87.6 mg versus 15.7 mg, p = 0.001). Mean amount of opioids used by patients over surgical course was reduced by 42% from pre-intervention to post-intervention; however, there was not a significant difference between the two groups (24.2 mg PrI versus 13.7 mg PoI, p = 0.367). Pain scores measured on postoperative day 1, discharge and follow up were not significantly different between the pre- and post- intervention groups, Table 3.

Discussion

Postoperative narcotics remain a significant source of opiate exposure for MIS patients and an opportunity for improvements in clinical prescribing habits. Our single-institution study, which is one of the first prospective trials to evaluate postoperative pain control and patient-reported outcomes, demonstrated that a standardized pain protocol with an "opt-in" requirement for prescription of opiates, non-narcotic medications as the first line for pain control, and patient education, had a significant impact on opioid use in postoperative patients. Firstly, analyses of the entire cohort and the prostatectomy cohort found that approximately 70% of patients in the PoI group were discharged without any narcotic prescription. These results are similar to the 67.7% reduction found by Talwar et al.[12] In our general cohort,

TABLE 3. **Radical prostatectomy subgroup analysis**

	Prl (n = 16)	Pol (n = 21)	p value[a]
Postoperative			
Patients receiving narcotics, n (%)	10 (62.5%)	15 (71.4%)	0.565
MED (mg, mean[b] [95% CI[b]])	9.2 [3.4, 25.3]	10.8 [5.1, 23.1]	0.792
MED (mg, median (Q1-Q3))	20 (0-46.3)	20 (0-38.8)	
NRS pain score, mean (SD), [95% CI]	3.1 (2.3), [1.8, 4.3]	3.6 (2.7), [2.4, 4.8]	0.721
Discharge			
Patients discharged on narcotics, n (%)	16 (100.0%)	6 (28.6%)	< 0.001
MED (mg, mean[b] [95% CI[b]])	64.6 [56.2, 74.1]	3.2 [1.4, 7.7]	< 0.001
MED (mg, median (Q1-Q3))	75 (60-75)	0 (0-38.8)	
NRS pain score, mean (SD), [95% CI]	3.1 (2.5), [1.7, 4.4]	3.7 (2.7), [2.5, 4.9]	0.598
Follow up			
Patients receiving additional narcotics, n (%)	0 (0%)	2 (9.5%)	0.288
MED (mg, mean[b] [95% CI[b]])	-	1.5 [0.8, 2.7]	0.163
MED (mg, median (Q1-Q3))		-	-
NRS pain score, mean (SD), [95% CI]	1.1 (1.8), [0.2, 2.1]	1.0 (1.5), [0.3, 1.7]	0.700
MED over entire surgical course			
Prescribed (mg, mean[b] [95% CI[b]])	87.6 [70.5, 108.8]	15.7 [6.4, 38.7]	0.001
Used (mg, mean[b] [95% CI[b]])	24.2 [8.6, 68.2]	13.7 [6.0, 31.3]	0.367

[a]p value corresponds to t-test of logged data for MED variables, Mann-Whitney test for continuous variables (NRS pain scores), and χ2test for categorical variables
[b]geometric mean and its 95% confidence interval
MED = morphine equivalent doses; SD = standard deviation; CI = confidence interval; Q1 = lower quartile; Q3 = upper quartile; NRS = numerical rating scale

there were significant reductions in the amount of opioids prescribed at discharge, the amount used during follow up, and the overall amount of opioids prescribed over surgical course in the PoI group. Importantly, we found that there was no difference in the number or amount of narcotics prescribed in the postoperative period between the PrI and PoI groups. This indicates that patients experience significant pain in the postoperative period that may require narcotics. However, when considered in combination with the significant difference in opioid prescription at discharge (secondary to the "24 hour rule" of the intervention) between PrI and PoI, it becomes clear that patients generally do not need to be sent home with an opioid prescription. This is consistent with previous studies that found that the majority of discharge narcotics were not utilized.[8,10,11] The results of this intervention highlight a targeted approach to narcotic prescription reduction: while patients may need narcotics initially, it is appropriate to discontinue or significantly reduced these medications at discharge without compromising patient comfort.

In this study's prostatectomy cohort, there were similarly significant reductions in the amount of opioids prescribed at discharge and over the entire surgical course. RALP procedures often result in a hospitalization of 1 day; despite this, many patients were able to be discharged without narcotic prescriptions, as they had not required narcotics in the preceding 24 hours. This seeming discrepancy is likely due to the differing nature of these calculations: length of stay was recorded as a whole number (thus not reflecting a portion of a day stayed), while a provider deciding to prescribe narcotics was able to specifically look at the past 24 hours in a patient's chart at discharge. These results reflect the importance of the "24-hour" rule, as it allows providers to base narcotic prescriptions on a more accurate picture of a patient's needs.

Finally, and most importantly, the reductions noted in each analysis were not associated with any significant difference in pain scores at any time point between the pre- and post- intervention group. While the PENN study also found no significant difference in pain between patients discharged with and without opioids,[12] it is difficult to make further comparisons, as there was not a pre- and post- intervention analysis of opioid prescribing habits or pain scores. Similarly, the ORIOLES study[15] found that a three-part intervention resulted

changes in prescribing habits without a difference in postoperative pain; however, the study evaluated only the presence of incisional/post-surgical pain at 30 days, rather than evaluating differences in patient pain ratings at multiple time intervals soon after surgery.

This study indicates that many MIS patients can be prescribed non-narcotic pain medication in the post-surgical period without negatively affecting pain control. We believe the "opt-in" requirement for opiates accounts for the dramatic decrease in prescription over patients' entire surgical course between the two groups. This requirement - while an additional step for health care professionals - provides a vital period of reflection on the benefits versus risks of opiates in individual patients, and acts as a "check" on their prescription. Equally important appears to be the "24-hour" rule, where patients in the PoI group only receive opiates at discharge if required in their final 24 hours of inpatient care. We posit that this accounts for the dramatic decrease in opioids prescribed at discharge. Our results also show that while a few patients required additional narcotic prescriptions between discharge and follow up, the majority did not. Surgeons can be reassured by this- most patients will not be in pain and unable to access medications to make themselves comfortable (a commonly cited concern and reason for significant prescriptions at discharge). Finally, we believe that patient education in the form of standardized discharge instructions is critical to empowering patients and increasing their knowledge. Anecdotal reports from participants in the study cited the discharge instructions as being a helpful way to gauge the "appropriateness" of their pain.

Limitations to this study include the small sample size and the use of a subjective pain scale. Additionally, this study was subject to recall bias. Although the majority of patients brought in their narcotics pills for a pill count (as instructed in the discharge paperwork), a few patients relied on memory when reporting how many they had taken. Further studies are necessary to continue to evaluate the efficacy of this protocol in larger, more diverse surgical cohorts. The effectiveness of patient education on pain expectations should be investigated and optimized. Finally, the applicability of this protocol to other types of minimally invasive cases outside the field of urologic oncology should be examined.

Conclusion

The opioid epidemic is a national healthcare emergency that warrants increased physician engagement. With a growing understanding of the personal and societal cost of opioid addiction, surgeons must participate in policy changes to help reduce opiate use. This study highlights the importance of patient education and an "opt-in" model of postoperative pain management in significantly reducing opiate utilization. □

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