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ORIGINAL ARTICLE

Incidence of venous thromboembolism in benign urologic reconstructive cases

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Abstract

Purpose To evaluate the rate of perioperative venous thromboembolism (VTE) among patients undergoing common benign urologic reconstructive cases. We hypothesize that this rate will be lower than previously described.

Methods We utilized the American College of Surgeons National Surgical Quality Improvement Project database from 2015 to 2019 to evaluate 30-day perioperative risk of VTE. Patients ≥ 18 years old undergoing benign urologic reconstructive cases were selected using Current Procedural Terminology (CPT) codes. Demographic, comorbidity, and operative variables were captured. The primary outcome was VTE within the 30-day postoperative period.

Results We identified 8467 patients who met inclusion criteria. The majority of patients were male (> 95%) with an average age of 65 and BMI of 29.6. There were 23 VTE events (0.27%) within the 30-day perioperative period. Fourteen (14/59) procedures had a perioperative VTE. Many of the traditional factors for VTE including operative time and obesity significantly increased risk of VTE in univariate analysis. In multivariate analysis, only BMI (OR 1.09; 95% CI 1.01–1.12) and inpatient status (OR 4.42; 95% CI 1.9–10.2) were correlated with increased perioperative VTE.

Conclusion The rate of VTE among patients undergoing benign urologic reconstructive cases is low. Providers should continue to have high index of suspicion particularly for inpatients with high BMI in addition to other known risk factors for VTE.

Keywords Venous thromboembolism (VTE) · Deep vein thrombosis (DVT) · Pulmonary embolism · Reconstructive urology · ACS-NSQIP

Abbreviations

ACS	NSQIP or NSQIP—American College of Surgeons National Surgical Quality Improvement Program
ASA	Anesthesia society of America
AUA:	American urological association
BMI	Body mass index
COPD	Chronic obstructive pulmonary disease
CPT	Current procedural terminology
EAU	European association of urology
VTE	Venous thromboembolism
SD	Standard deviation

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Introduction

Venous thromboembolism (VTE) is a potentially life-threatening perioperative complication. The diagnosis of VTE is a reportable outcome and includes deep vein thrombosis (DVT) and pulmonary embolism (PE) [1]. While anyone can experience VTE, the perioperative period is high-risk time for VTE [2]. Due to this increase in risk and to better identify patients who are at the highest risk of VTE, validated risk scores have been designed across surgical fields [3]. To mitigate the risk of VTE and in accordance with risk scoring and/or academy guidelines, surgeons routinely employ either mechanical [e.g., sequential compression devices (SCDs)], or chemo/pharmaceutical (e.g., heparin) prophylaxis.

Recommendations for VTE prophylaxis have been a source of significant research interest across multiple

surgical specialties culminating in the creation of national and hospital specific guidelines [4]. Within Urology, the American Urological Association (AUA) and European Association of Urology (EAU) put forth recommendations for VTE prophylaxis in 2008, and 2017, respectively [5, 6]. The rate of symptomatic VTE in patients undergoing major urologic surgery is highly variable based on patient risk and surgical intervention ranging from 0 to 4% [7]. A large review highlighted the broad nature of AUA guidelines and the highly variable VTE rate in Urologic surgery [8]. This is largely due to a continued paucity of the literature on the role of benign urologic procedures. Current guidelines (both AUA and EAU) group incontinence/pelvic reconstructive surgery and many of the recommendations are low strength of evidence [6]. Furthermore, despite numerous case-specific recommendations for oncologic procedures, neither the AUA nor the EAU offers procedure-specific recommendations for VTE prophylaxis in common reconstructive urologic cases.

We sought to describe the VTE rate in the perioperative period in patients undergoing common benign urologic reconstructive cases. We hypothesized that amongst men and women undergoing benign reconstructive cases, only those with multiple comorbid VTE risk factors would be susceptible to VTE with a very low overall rate.

Patients and methods

Data source

We utilized the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP), which captures clinical data and postoperative complications for patients undergoing major surgical procedures at more than 700 voluntarily participating institutions. Outcomes, including VTE, are tracked within the 30-day postoperative period. The methods of the ACS-NSQIP data collection process were previously described and validated [9]. We, respectively, reviewed data from the ACS-NSQIP database from 2015 through 2019. Given the nature of the database (national database without patient identifiers) we obtained institutional review board exemption from our institution.

Study population

Patients undergoing index benign urologic reconstructive cases were selected using Current Procedural Terminology (CPT) codes for the following procedures in men and women age $\geq$ 18 years: artificial urinary sphincter (AUS) (CPT 53444, 53445, 53446, 53447, 53448, 53449); cystoscopy treatment of urethral stricture and/or bladder neck contracture (CPT 52276, 53600, 53601,52281, 52500, 52640); gender affirming surgery (CPT 55970, 55980, 56800, 56805, 56810, 57335); male urethral sling (CPT 53440, 53442); Peyronie's repair (CPT 54110, 54111, 54112, 54115, 54300, 54304); scrotoplasty (CPT 55150, 55175, 55180); urethroplasty (CPT 53000, 53010, 53400, 53405, 53410, 53415, 53420, 53425, 53430, 53431, 53450, 53460, 53500, 53515, 53520, 54308, 54312, 54316, 54318, 54322, 54324, 54326, 54328, 54332, 54340, 54344, 54348, 54352, 54360, 54380).

Concomitant surgeries were allowed if they were within the CPT codes queried. Patients—for example—with concomitant urethroplasty and scrotoplasty were included but patients with urethroplasty and cystectomy were excluded. The NSQIP database has not included penile prosthesis surgery since 2014, thus our analysis does not include any patients undergoing placement of penile prostheses. Additionally, intra-abdominal reconstruction including benign cystectomy, ureteral reimplantation and trauma were excluded due to the high predicted variability in VTE risk and prophylaxis among this patient population. Finally, patients with 'disseminated malignancy' were excluded.

Study endpoint

Our primary outcome was VTE within the 30-day postoperative period, including PE and DVT. Per ACS-NSQIP, PE diagnosis is defined as "a blood clot in the pulmonary artery with subsequent obstructions of blood supply to the lung parenchyma, confirmed by a ventilation-profusion scan interpreted as 'high probability' of PE or a positive computed tomography spiral examination, pulmonary arteriogram, or computed tomography angiogram". Similarly, DVT as defined by ACS-NSQIP was "The identification of a new blood clot or thrombus within the venous system, which may be coupled with inflammation within 30 days of the operation. This diagnosis is confirmed by a duplex, venogram or CT scan. The patient must be treated with anticoagulation therapy and/or placement of a vena cava filter or clipping of the vena cava" [10]. Demographic (age, sex, race, body mass index (BMI)), comorbidities (yes/no) (diabetes mellitus, smoking status, steroid use, hypertension requiring medication, renal failure, chronic obstructive pulmonary disease, congestive heart failure), preoperative dyspnea, functional status (independent, partially dependent, totally dependent), American Society of Anesthesiologists' (ASA) physical status), and operative (operative time, type of anesthesia, elective surgery, in/outpatient surgery) variables were captured as potential risk factors for VTE.

Based on the AUA VTE risk stratification, most patients underwent "minor" surgery and/or would fall into the low and moderate risk, which would not require pharmaceutical thromboprophylaxis. The NSQIP database does not include thromboprophylaxis. Prior studies have assumed surgeons

followed national guidelines, however, we provide these data for context only [11–13].

Statistical analysis

Descriptive statistics were reported as frequency (%) for categorical, mean [standard deviation (SD)] for normally distributed continuous, and median [interquartile range (IQR)] for non-normally distributed continuous variables. We reported the cumulative incidence of VTE by 30 days after surgery in the studied population. Characteristics of patients who had a VTE event were compared to those who did not using chi-square or Fisher exact test for categorical variables, and *t* test or Mann–Whitney test for continuous variables. Multivariable logistic regression was performed with backward selection and considered factors with $p < 0.1$ in univariate analysis. Model goodness-of-fit was assessed with Hosmer–Leeshawn goodness-of-fit test [14]. The assumption of linearity of BMI in the regression model was checked using restricted cubic splines. Given a baseline risk of approximately 0.1% annually for spontaneous DVT in the population and a minimum expected rate of 0.7% among patients undergoing urologic surgery, the study was powered with an $\alpha = 0.01$ and $\beta = 0.05$ with patient sample of 1327 [8, 15]. All *p* values were two-sided with a value < 0.05 considered statistically significant. The design and reporting of the study followed the STROBE guidelines and checklist for observational studies [16].

Results

We identified 8467 patients meeting inclusion criteria who underwent a qualifying reconstructive surgery during the study period. The majority of patients were male (> 95%) with an average age of 65 and average BMI of 29.6 (Table 1). The cumulative incidence of VTE within the first 30 days after surgery was 0.27% (23 events). There were nine deaths in the cohort (0.11%) within the 30-day perioperative period. One patient died with a recorded VTE; it was not the listed cause of death. The cases that had an associated VTE within the study period are summarized in Table 2. Female urethroplasty and second-stage urethroplasty were associated with the highest rates of VTE with 0.93% and 4.35%, respectively. Cystoscopy with bladder neck incision and first-stage urethroplasty were both associated with the greatest absolute number of VTE events ($n = 4$; 0.24%).

Univariate analysis demonstrated significant associations between VTE event and BMI, inpatient status, operative time, renal failure, and American Society of Anesthesiologists classification (ASA). On multivariate analysis, only BMI and inpatient status were associated with increased risk of VTE (Table 3). The odds ratio on multivariate analysis were significant for BMI (OR 1.09; 95%CI 1.01–1.12; $p = 0.013$) and most strikingly for inpatient status (OR 4.42; 95%CI 1.9–10.2; $p = 0.001$). Age, diabetes, smoking status, steroid use, chronic obstructive pulmonary disease (COPD), and hypertension were not associated with VTE in the perioperative setting. The predicted probability of VTE occurrence according to BMI and inpatient status derived by the logistic regression model are depicted in Fig. 1.

Discussion

To our knowledge, this is the largest study examining patients undergoing benign urologic reconstructive cases. We observed a very low risk of VTE in patients undergoing benign urologic reconstructive cases (under 0.3%). This aligns with the literature among patients undergoing female pelvic reconstructive surgery [11, 12]. Interestingly, traditional risk factors for VTE including age, heart disease, lung disease, operative time, and smoking were not associated with VTE in multivariate analysis. Some of these factors including age and diabetes did not demonstrate significance in univariate analysis. It is possible that the traditional factors were appropriately mitigated by prophylaxis or that unmeasured factors were more significant. Given the nature of the procedures, we hypothesize that lithotomy and high lithotomy positioning may account for unmeasured VTE risk.

Prior publications have reported a highly variable rate of VTE in patients undergoing urologic procedures, primarily due to the focus on urologic oncology given higher rates of VTE in that population [8]. For example, for high-risk urologic oncology surgeries such as cystectomy the postoperative VTE range has been reported to be as high as 2.8–5% even with thromboprophylaxis [7, 8]. Surveys among Society of Urologic Oncology members indicate a heightened focus on VTE and a broad range of prophylaxis strategies to address the variable VTE rate [17]. The 2017 guidelines from the EAU incorporate highly specific procedural recommendations to address the wide range of VTE rate in patients undergoing oncologic operations. The EAU guidelines offer specific perioperative VTE recommendations for urologic cancer operations (e.g. different recommendations for open and laparoscopic prostatectomy) but group patients undergoing reconstructive surgery and note low strength of evidence for those recommendations [6]. The AUA similarly group all pelvic and reconstructive surgery and the recommended use of mechanical and chemical prophylaxis differs significantly from the EAU guidelines [5]. Depending on the interpretation of "minor surgery", AUA best practice may recommend dual prophylaxis, while the EAU recommends only early ambulation for the same patient undergoing the

Table 1 Characteristics of study population

	Total No. (%)	No VTE No. (%)	VTE No. (%)	*p* value[1]
N	8467	8444	23	
Age, median (IQR)	65 (53, 73)	65 (53, 73)	69 (55, 75)	0.53
Sex				0.98
Male	8017 (94.7)	7995 (94.7)	22 (95.7)	
Female	448 (5.3)	447 (5.3)	1 (4.3)	
Non-binary	2 (< 1)	2 (< 1)	0	
Race				0.57
White	5581 (65.9)	5568 (65.9)	13 (56.5)	
Black or African American	899 (10.6)	894 (10.6)	5 (21.7)	
Asian	234 (2.8)	234 (2.8)	0	
American Indian or Alaska native	43 (0.5)	43 (0.5)	0	
Native Hawaiian or Pacific Islander	33 (0.4)	33 (0.4)	0	
Unknown/not reported	1677 (19.8)	1672 (19.8%)	5 (21.7)	
BMI, mean (SD)	29.6 (5.98)	29.6 (5.98)	32.9 (5.61)	**0.008**
In/Out-patient				**< 0.001**
Outpatient	6303 (74.4)	6294 (74.5)	9 (39.1)	
Inpatient	2164 (25.6)	2150 (25.5)	14 (60.9)	
Anesthesia				0.99
General	7960 (94.0)	7937 (94.0)	23 (100.0)	
Spinal	266 (3.1)	266 (3.2)	0	
MAC/IV Sedation	219 (2.6)	219 (2.6)	0	
Local	7 (0.1)	7 (0.1)	0	
Other	5 (0.1)	5 (0.1)	0	
Regional	5 (0.1)	5 (0.1)	0	
Epidural	2 (< 1)	2 (< 1)	0	
None	2 (< 1)	2 (< 1)	0	
Unknown	1 (< 1)	1 (< 1)	0	
Elective surgery?				0.098
Yes	7917 (93.5)	7898 (93.5)	19 (82.6)	
No	543 (6.4)	539 (6.4)	4 (17.4)	
Unknown	7 (0.1)	7 (0.1)	0	
Operative time, median (IQR)	71 (34, 124)	71 (34, 124)	102 (62, 147)	**0.026**
Diabetes Mellitus				0.75
No	6791 (80.2)	6774 (80.2)	17 (73.9)	
Non-insulin	1107 (13.1)	1103 (13.1)	4 (17.4)	
Insulin	569 (6.7)	567 (6.7)	2 (8.7)	
Smoke				0.49
No	7397 (87.4)	7378 (87.4)	19 (82.6)	
Yes	1070 (12.6)	1066 (12.6)	4 (17.4)	
Functional status				0.89
Independent	8244 (97.4)	8221 (97.4)	23 (100)	
Partially Dependent	128 (1.5)	128 (1.5)	0	
Totally Dependent	26 (0.3)	26 (0.3)	0	
Unknown	69 (0.8)	69 (0.8)	0	
Steroid				0.6
No	8245 (97.4)	8223 (97.4)	22 (95.7)	
Yes	222 (2.6)	221 (2.6)	1 (4.3)	
Dyspnea				0.45
No	8129 (96)	8108 (96)	21 (91.3)	
Moderate exertion	320 (3.8)	318 (3.8)	2 (8.7)	

Table 1 (continued)

	Total No. (%)	No VTE No. (%)	VTE No. (%)	*p* value[1]
At rest	18 (0.2)	18 (0.2)	0	
COPD				0.24
No	8131 (96.0)	8110 (96.0)	21 (91.3)	
Yes	336 (4.0)	334 (4)	2 (8.7)	
Congestive Heart Failure (CHF)				0.67
No	8399 (99.2)	8376 (99.2)	23 (100)	
Yes	68 (0.8)	68 (0.8)	0	
Hypertension requiring medication				0.96
No	4099 (48.4)	4088 (48.4)	11 (47.8)	
Yes	4368 (51.6)	4356 (51.6)	12 (52.2)	
Renal failure				**< 0.001**
No	8442 (99.7)	8420 (99.7)	22 (95.7)	
Yes	25 (0.3)	24 (0.3)	1 (4.3)	
ASA status				**0.003**
1-Healthy	695 (8.2)	692 (8.2)	3 (13)	
2-Mild Disturb	3851 (45.5)	3844 (45.5)	7 (30.4)	
3-Severe Disturb	3651 (43.1)	3642 (43.1)	9 (39.1)	
4-Life Threat	249 (2.9)	245 (2.9)	4 (17.4)	
5-Moribund	2 (< 1)	2 (< 1)	0	
None assigned	19 (0.2)	19 (0.2)	0	

ASA Anesthesia society of America, *BMI* Body mass index, *COPD* Chronic obstructive pulmonary disease
[1]All p values represent tests comparing VTE vs no VTE groups

Table 2 VTE Risk by procedure code

CPT	Description	*N* at risk	*n* VTE (%)
52500	(Transurethral resection bladder neck)	1649	4 (0.24)
53410	(Urethroplasty 1 stage reconstruction male anterior urethra)	1049	4 (0.38)
53440	(Sling operation correction male urinary incontinence)	695	3 (0.43)
53445	(Iinflatable urethral/bladder neck sphincter)	1153	2 (0.17)
52640	(Tranurethral resection postop bladder neck contracture)	576	1 (0.17)
53400	(Urethroplasty 1st stage fistula/diverticulum/stricture)	260	1 (0.38)
53405	(Urethroplasty 2nd stage w/urinary diversion)	23	1 (4.35)
53415	(Urethroplasty transpubic/perineal 1 stage reconstruction/repair urethra)	463	1 (0.22)
53420	(Urethroplasty 2-stage reconstruction/repair prostate/urethra 1st stage)	36	1 (2.78)
53430	(Urethroplasty reconstruction/repair female urethra)	108	1 (0.93)
53447	(Removal & replacement inflatebale urethral/bladder neck sphincter)	345	1 (0.29)
54360	(Plastic repair penis correct angulation)	337	1 (0.3)
55150	(Resection scrotum)	209	1 (0.48)
55175	(Scrotoplasty simple)	137	1 (0.73)
Total (of above codes)		7040	23 (0.33)

same surgery [5, 6]. What this leaves is a void between broad guidelines and specific clinical practice where more information is needed. Groups have begun to investigate the optimal VTE prophylaxis in specific benign reconstructive cases such as urethroplasty [18]. We hope that this study continues to support the notion that benign urologic surgery should not be grouped with oncologic operations from the standpoint of VTE risk. Furthermore, more research is needed to better understand practice patterns amongst urologists performing reconstructive pelvic surgery to further inform and increase the strength of evidence of future guideline statements.

Table 3 Multivariable analysis of factors associated with VTE occurrence in 30-day postoperative period.

	Univariate			Multivariable		
	Odds ratio	95% CI	*p* value	Odds ratio	95% CI	*p* value
BMI (continuous)	1.07	1.02–1.12	**0.007**	1.06	1.01–1.12	**0.013**
Inpatient (vs outpatient)	4.55	1.97–10.5	**< 0.001**	4.4	1.91–10.2	**0.001**
Elective surgery	0.57	0.33–0.98	**0.042**	0.94	0.48–1.8	0.843
Operative time (continuous)	1.003	0.99–1.008	0.102	1.001	0.99–1.006	0.421
Renal failure	15.9	2.06–123	**0.008**	4.0	0.44–37	0.218
ASA status (vs no disturb)						
2-Mild Disturb	0.42	0.11–1.63	0.21	0.42	0.11–1.65	0.218
3-Severe Disturb	0.57	0.15–2.11	0.4	0.51	0.13–1.95	0.324
4-Life Threat	3.77	0.84–16.9	0.08	2.4	0.51–11.6	0.267
5-Moribund	No observations			No observations		

P values highlighted in bold indicate statistical significance

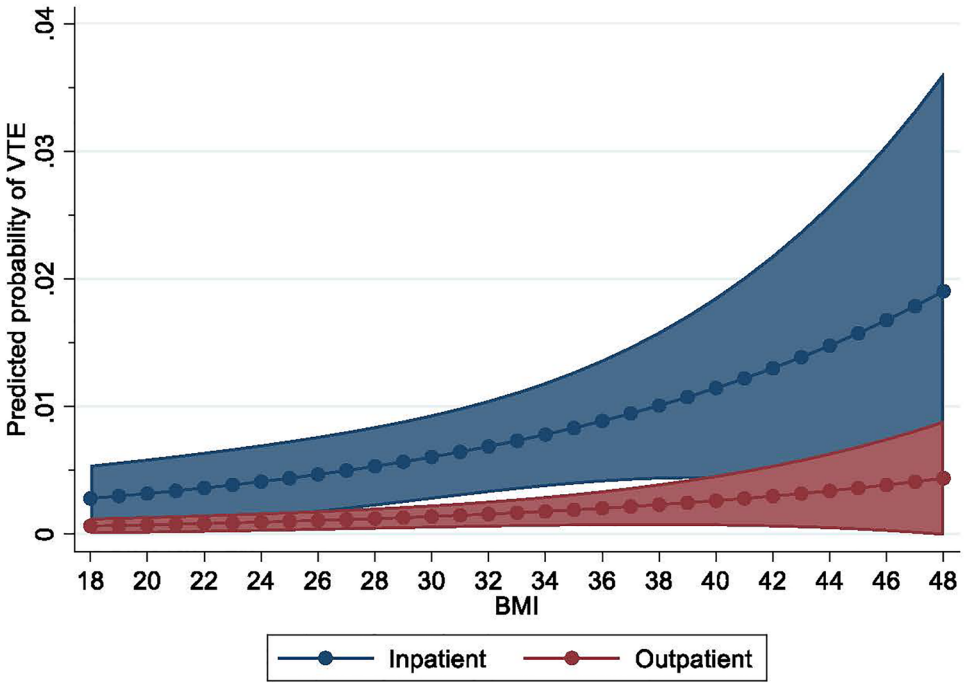

Fig. 1 Logistic regression model predicted probabilities of VTE. Shaded areas represent 95% confidence intervals

There are a few key limitations to this study which should be noted. First and foremost, the NSQIP dataset does not include data on the use of VTE prophylaxis. Therefore, it is not possible to comment on the appropriateness of the VTE prophylaxis. Furthermore, while the dataset includes both incidental VTE and symptomatic VTE, there is a potential for underreporting of outcomes, particularly asymptomatic VTE. Given our finding that female urethroplasty was among the higher risk procedures, there is the possibility of the unmeasured risk based on use oral contraceptives (OCP). OCP use has been associated with up to a fourfold increase in VTE over baseline risk and OCP status is not reported in the dataset [19].

The purpose of this study was to describe the rate of VTE in benign reconstructive urologic surgeries. It has been well established that malignancy is an independent risk for VTE, and this study is the largest study examining VTE risk specifically in the reconstructive population. Despite that, given the low number of VTE events, translating the results to clinical practice is challenging. Furthermore, among the patients who experienced VTE there was collinearity between variables in the multivariate

model. This can lead to some relevant factors dropping out of the model or errors in interpretation. Absence of statistical significance in the multivariate analysis does not imply absence of a clinically significant event. This likely accounts for why some factors known to increase VTE risk were not significant in our analysis.

As discussed in the methods this study also did not include men undergoing penile prosthesis which could incorporate men with potentially high-risk cardiac comorbidities. Our analysis may underestimate the rate of VTE by excluding this population. Additionally, NSQIP captures patients with "disseminated malignancy" (who were excluded from our analysis), but history of malignancy is not captured. Given the number of patients who were undergoing cancer survivorship operations (e.g., cystoscopy with dilation of bladder neck or placement of artificial urinary sphincter), malignancy history may be an uncaptured confounder. We suggest that this uncaptured variable would make our measured rate an overestimate. Finally, a single outlier (patient with BMI > 75) was excluded from analysis (they did not experience a DVT).

To address the continued data gap between recommended VTE prophylaxis and provider practice patterns, our group aims to assess national and international practice patterns among providers for index reconstructive cases. Furthermore, collaborative efforts to capture VTE rates among populations where prophylaxis is known will be crucial for new guidelines and improved strength of evidence.

Conclusion

The rate of VTE among patients undergoing benign urologic reconstructive cases is very low. Providers should continue to have a high index of suspicion particularly for inpatients with high BMI. Current VTE prophylaxis practice patterns should be studied and codified to better offer guidelines for reconstructive patients.

Author contributions NS: project design, data analysis, manuscript draft. NH: data collection, data analysis, manuscript draft. JL: data collection, critical review. BN: data analysis and support. KL: critical review. PL: critical review. BA: critical review. BB: supervision, project design, critical review.

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Declarations

Conflict of interest All authors acknowledge the policy regarding competing interests. All authors declare no conflict of interest.

Ethical approval This work does not involve human participants nor animal subjects. Ethical approval was waived by the Institutional Review Board (IRB) as all data were from de-identified database.

Informed consent As there were no human subjects and no identifiable patient data, informed consent was similarly waived.

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