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ORIGINAL RESEARCH

Hemopatch® as a Hemostatic Agent is Safe in Partial Nephrectomy: A Large, Single-Surgeon Retrospective Evaluation

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ABSTRACT

Introduction: Partial nephrectomy (PN) has evolved into the surgical standard of care for localized renal lesions. Hemostatic agents (HA) support the surgeon in achieving local hemostasis during PN. We previously reported initial results with the HA Hemopatch® in PN. We now report our experiences with Hemopatch® in a larger and more challenging single-surgeon PN cohort.

Methods: Our study included 45 patients who underwent PN due to suspicious renal lesions between December 2013 and March 2018. All surgeries were performed by a single surgeon using the HA Hemopatch®. Preoperative, intraoperative, and postoperative parameters were assessed.

Results: Preoperative median tumor diameter was 27 mm. Median PADUA and RENAL nephrometry scores were 7 and 6, respectively. In 13.3% of the cases an additional HA was applied. Intraoperative and postoperative bleeding occurred in 2.2% and 8.9%, respectively. Median total blood loss was 200 ml. Urgent pedicle clamping due to bleeding was necessary in 2 (4.4%) patients. The transfusion rate was 8.9%. There were no conversions.

Conclusion: We confirmed our initial results demonstrating feasibility and reliability of Hemopatch® during PN. Notably, the cohort consists of selected patients. Prospective randomized studies are needed for comparison of different types of HA with regard to perioperative outcome.

Keywords: Clavien–Dindo; Hemopatch; Hemostatic agent; Nephrology; NSS; Partial nephrectomy

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Key Summary Points

Partial nephrectomy has evolved into the surgical standard of care for localized renal lesions.

Hemostatic agents support the surgeon in achieving local hemostasis during partial nephrectomy.

Initial results of a case series utilizing the hemostatic agent Hemopatch® in partial nephrectomy demonstrated safety.

In this larger and more challenging cohort, feasibility and reliability of Hemopatch® during partial nephrectomy were confirmed.

DIGITAL FEATURES

This article is published with digital features, including a summary slide, to facilitate understanding of the article. To view digital features for this article go to https://doi.org/10.6084/m9.figshare.13247318.

INTRODUCTION

Recent advances in techniques of renal surgery [1] resulted in a shift towards nephron-sparing and minimally invasive approaches [2]. While the rate of open radical nephrectomies decreased between 2002 and 2010 (54–29%), laparoscopic radical nephrectomies increased (30–39%). The rate of open partial nephrectomy (PN) remained stable (around 15%), while the proportion of laparoscopic PN increased (2–17%) [2]. PN is recommended for all T1 tumors and for T2 tumors (if technically feasible) [3]. It can be performed either with open or minimally invasive approach dependent on the surgeon's skills [3]. Bleeding is a main complication of PN (severe hemorrhage 3.1% vs. 1.2% radical nephrectomy) [4, 5]. Intra- and postoperative bleeding is surgically anticipated by coagulation, suturing, as well as with the use of hemostatic agents (HAs) or tissue sealants [5].

HAs, e.g., fibrin/thrombin-based, gelatin-based, or hydrogel-based, were shown to accelerate hemostasis and sealing [6]. They are predominantly applied during minimally invasive PN compared to open PN: 67.6% for open PN, 75.6% for laparoscopic PN, and 80.9% for robot-assisted PN ($p = 0.024$) [7]. The HA Hemopatch® (Baxter International Inc., Deerfield, IL, USA) is a resorbable, collagen-based, and *N*-hydroxyl-succinimide-functionalized polyethylene glycol (NHS-PEG)-coated patch [8, 9]. The coating is protein reactive and enables fast adherence of the patch to the wound. Within the collagen fibers, platelets form a clot and start the clotting cascade [10, 11]. The application of Hemopatch® can result in successful hemostasis within 2 min across different types of surgeries [12].

In 2015, our working group reported our initial experience with Hemopatch® in seven patients who underwent zero-ischemia laparoscopic PN, and Hemopatch® successfully achieved hemostasis in all cases [13].

We now report the results and real-life data of our expanded Hemopatch® cohort comprising 45 patients who underwent PN performed by one single surgeon.

METHODS

Our study included 45 patients who underwent PN because of suspicious renal lesions at the Department of Urology of Hannover Medical School between December 2013 and March 2018 either via open or laparoscopic approach.

Inclusion criteria were the following: (i) all surgeries were performed by a single surgeon (FI) and (ii) in all surgeries Hemopatch® was applied as HA.

Hemopatch® is a standard HA in our department as (i) it can be easily rolled, (ii) it can be easily transferred into the body through the laparoscopic trocar, (iii) it is non-clotting, and (iv) it perfectly adheres on the enucleation zone.

Multiple renal lesions (4/45 patients) were counted as one case for statistical analyses.

The surgical technique of the laparoscopic approach was analogous to the technique previously described by our working group [13], except that only half of the surgeries were performed with zero ischemia. Laparoscopic application of the Hemopatch® is also described and illustrated elsewhere [13].

We preferably sutured only the tumor bed. Usually we did not perform a renorrhaphy. We used the HA to achieve hemostasis of the parenchyma. In detail, a Hemopatch® pad was placed on top of the parenchyma suture covering the enucleation zone with an overlap of approximately 1 cm. Moderate pressure was applied to the Hemopatch® for 2 min to induce hemostasis and sealing [13]. Additional HAs used in this study were Floseal® or Traumastem® (both Baxter products as well). Open PN was performed through 11/12th intercostal lumbar incision.

Preoperative, intraoperative, and postoperative parameters were assessed (Tables 1, 2, 3). PADUA and RENAL nephrometry scores [14, 15] were preoperatively assessed by two independent experienced urologists. For RENAL nephrometry score assessment the amendments about localization (anterior/posterior) and hilar localization were excluded. Blood loss was measured using the irrigation suction system. Intraoperative bleeding was defined as uncontrolled bleeding requiring additional measures (excluding controlled pedicle clamping). Postoperative bleeding was defined as a postoperative intervention (coil embolization or surgery) to stop bleeding or a renal hematoma.

Complications were classified according to Clavien–Dindo [16].

Hemopatch® is certified for use in the territory of the European Union; therefore, approval from the institutional board was not required for its application. Furthermore, this study was granted exemption from requiring local ethics approval (Medical School Hannover) because of its retrospective design and because informed consent was obtained beforehand from all patients.

Descriptive statistics was performed with Microsoft Access, Microsoft Excel, and SPSS Statistics 25 from IBM.

The study was performed in accordance with the Helsinki Declaration of 1964, and its later amendments.

RESULTS

The median patient age at time of surgery was 64.9 years in our cohort (mean ± SD 63.1 ± 14.1).

Tumor Characteristics

Table 1 presents tumor characteristics. Approximately three-quarters ($n = 33/45$) of the patients had malignant renal lesions. The majority among the malignant lesions were clear cell renal cell cancer (RCC; 54.5%), pT1 (93.9%), and G1–2 (72.7%). Histopathologic assessment revealed a benign histology in $n = 12$ cases, including oncocytoma ($n = 6$), purulent renal tumor ($n = 1$), juxtaglomerular cell tumor ($n = 1$), angiomyolipoma ($n = 2$), renal cyst ($n = 1$), and leiomyoma ($n = 1$). Nine out of 10 tumors were single lesions and laterality was nearly equal (60.0 vs. 40.0%). Preoperative median PADUA and RENAL nephrometry score was 7 and 6, respectively.

Intra- and Postoperative Characteristics

Hemopatch® was exclusively applied in 40 out of 45 cases (88.9%; Table 2). In one case (2.2%), Hemopatch® was combined with Floseal® to improve hemostasis of the tumor bed. In four cases (8.9%) Hemopatch® was combined with Traumastem®. In two cases Traumastem® was used as a bolster on top of the Hemopatch® and in the remaining two cases Traumastem® was separately placed in the retroperitoneum to achieve local hemostasis. Surgery was performed under zero ischemia in 55.6% of the cases and laparoscopically in 88.9% of the cases. There were no conversions from laparoscopic to open PN surgery and no intended PN lead to consecutive radical nephrectomies. Intraoperative bleeding occurred in one patient (2.2%). Median total blood loss was 200 ml. The maximum blood loss was 1300 ml.

Table 1 Tumor characteristics

Parameters	Values
Age at surgery (median; mean ± SD) [years]	64.9; 63.1 ± 14.1
Histology	
Clear cell RCC	40.0% (18/45)
Papillary RCC	13.3% (6/45)
Chromophobe RCC	11.1% (5/45)
Miscellaneous or mixed renal malignancy	8.9% (4/45)
Benign	26.7% (12/45)
Diameter CT/MRI scan (median; mean ± SD) [mm]	27.0; 29.0 ± 13.0
Diameter pathology report (median; mean ± SD) [mm]	28; 29.3 ± 13.5
(for $n = 8$ no diameter indicated in the report)	
T stage	
pT1	93.9% (31/33)
pT2	0
pT3	6.1% (2/33)
pT4	0
Fuhrman grade	
1	21.2% (7/33)
2	51.5% (17/33)
3	3.0% (1/33)
4	0
Unknown	24.2% (8/33)
Numbers of tumors	
Single	95.6% (43/45)
Multiple	4.4% (2/45)
Localization	
Right	40.0% (18/45)
Left	60.0% (27/45)
PADUA score	
6	26.7% (12/45)
7	35.6% (16/45)
8	17.8% (8/45)
9	15.6% (7/45)
10	4.4% (2/45)
11	0
12	0
13	0
14	0
Median	7
RENAL score (excluding information about anterior/posterior)	
4	28.9% (13/45)
5	11.1% (5/45)
6	28.9% (13/45)
7	13.3% (6/45)
8	13.3% (6/45)
9	2.2% (1/45)
10	2.2% (1/45)
11	0
12	0
Median	6

CT computer tomography, *MRI* magnet resonance imaging, *RCC* renal cell cancer, *SD* standard deviation

Table 2 Intraoperative characteristics

Parameters	Values
Hemostatic agent	
Hemopatch® single	88.9% (40/45)
Hemopatch® plus Floseal®	2.2% (1/45)
Hemopatch® plus Traumastem®	8.9% (4/45)
Zero ischemia	
Yes	55.6% (25/45)
No	44.4% (20/45)
Surgical approach	
Open	11.1% (5/45)
Laparoscopic	88.9% (40/45)
Intraoperative bleeding	
Yes	2.2% (1/45)
No	97.7% (44/45)
Intraoperative pedicle clamping due to bleeding	
Yes	4.4% (2/45)
No	95.6% (43/45)
Conversion laparoscopic to open	
Yes	0
No	100% (40/40)
Operation time (median; mean ± SD) [min]	116; 119.8 ± 32.1
Ischemia time (median; mean ± SD) [min] (for n = 20 ischemia cases)	15.0; 15.3 ± 7.3
Total blood loss (median; mean ± SD) [ml] (n = 4 missing data)	200.0; 231.1 ± 230.0
Blood transfusion intra-/postoperative	
Yes	8.9% (4/45)
No	91.1% (41/45)

SD standard deviation

There were 4 (8.9%) postoperative bleedings (Table 3). The majority of patients (80%) had no postoperative complications. A Clavien–Dindo score of 3 was assigned to six cases of the cohort

Table 3 Postoperative characteristics

Parameters	Values
Postoperative bleeding	
Yes	8.9% (4/45)
No	91.1% (41/45)
Clavien–Dindo score	
0	80.0% (36/45)
1	2.2% (1/45)
2	4.4% (2/45)
3	13.3% (6/45)
4	0
5	0
Length of wound drainage (median; mean ± SD) [days]	2.0; 2.82 ± 1.5
Length of hospital stay (median; mean ± SD) [days]	6.0; 6.9 ± 3.4

SD standard deviation

because of laparotomy (n = 1)/laparoscopy (n = 1) due to bleeding, coil embolization due to bleeding (n = 1), DJ stenting due to urinoma (n = 2), and cardioversion due to atrial fibrillation (n = 1).

Characteristics of Bleeding Complications

Table 4 gives an overview of the cases with intra- and/or postoperative bleeding. The preoperatively assessed tumor diameter ranged up to 60 mm. PADUA and RENAL nephrometry score ranged up to 9 and 8, respectively.

One patient experienced intraoperative and postoperative bleeding, resulting in a total blood loss of 1300 ml (#1 in Table 4). This patient needed therapeutic anticoagulation and immunosuppression due to history of chronic thromboembolic pulmonary hypertension and subsequent lung transplantation. The renal artery could not be separated adequately

Table 4 Characteristics of all cases with intra-/postoperative bleeding

Parameters	Intraoperative bleeding ($n = 1$)	Postoperative bleeding ($n = 4$)
Number of tumors multiple/single	0/1	1/3
PADUA score	8	6; 8; 8; 9
RENAL score (excluding information about anterior/posterior)	8	6; 7; 8; 8
Diameter CT/MRI scan [mm]	20	20; 20; 25; 60
Hemopatch® exclusive/+Floseal®/+Traumastem®	1/0/0	3/1/0
Zero ischemia yes/no	1/0	3/1
Ischemia time [min]	0	9
Total perioperative blood loss [ml]	1300	200; 200; 300; 1300
Assessment of bleeding	#1 additional port for suction (see main text; Hemopatch®)	#1 postoperative laparotomy (see main text; Hemopatch®) #2 postoperative laparoscopy, coagulation of a blood vessel of the renal capsule (Hemopatch®) #3 postoperative coil embolization due to gross hematuria, anticoagulation (Hemopatch®) #4 postoperative renal hematoma (Hemopatch® + Floseal®)

CT computer tomography, *MRI* magnet resonance imaging

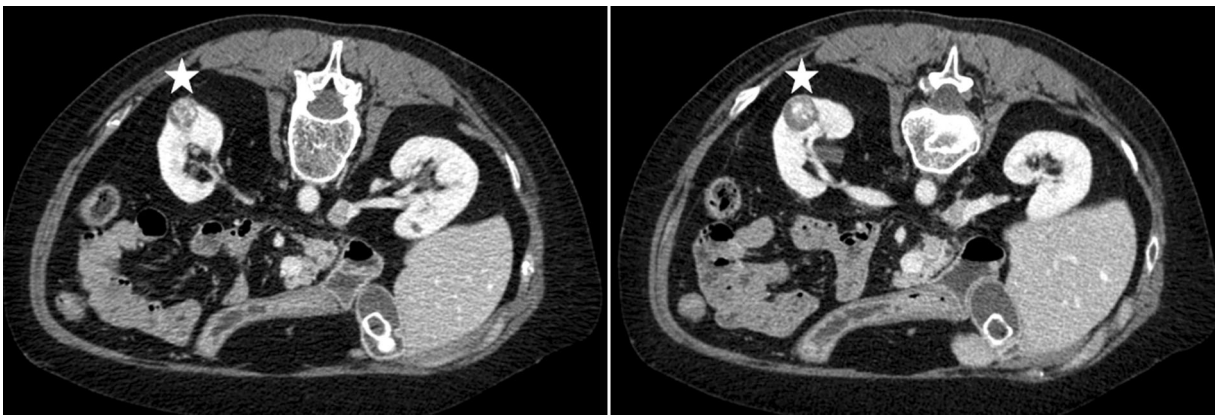

Fig. 1 Exemplary preoperative CT scans of one case (patient #1 in Table 4) with intra- and postoperative bleeding (transverse plane; renal lesion in left kidney marked with a star)

because of adhesions of the renal hilum. The tumor appeared hypervascular. The surgery was performed laparoscopically with zero ischemia and Hemopatch® exclusively as HA. An additional port for suction was necessary to handle intraoperative bleeding. On postoperative day 1, a laparotomy (via Chevron incision) was performed because of postoperative bleeding. Length of wound drainage and hospital stay were 11 and 19 days, respectively. The complication was classified as Clavien–Dindo 3. In total, 10 erythrocyte concentrates and six fresh frozen plasma transfusions were applied. This single tumor was preoperatively assessed as 20 mm in width, PADUA score 8, and RENAL nephrometry score 8. Preoperative scans of this case are shown in Fig. 1. Histopathologic evaluation revealed a clear cell RCC, pT1a G2 pR0.

The remaining patients who suffered from postoperative bleeding are characterized in Table 4.

DISCUSSION

There are a variety of HA products from different companies available for PN. The choice of HA is mainly based on the surgeon's individual experience. In this study we report the results and real-life data of our expanded Hemopatch® cohort comprising 45 patients who underwent PN performed by one single surgeon. The main results of our study are the following. There were only 13.3% major complications (all Clavien–Dindo 3). In general, the frequency of bleeding complications was low (urgent pedicle clamping due to bleeding in only every 23rd patient (4.4%), blood transfusion in only every 11th patient (8.9%), and median total blood loss of 200 ml. There were no conversions from laparoscopic to open surgery and the median operation time was short (116 min).

In our series severe bleeding occurred in the majority of the cases as a result of patient-related factors (Table 4; patients #1–3). An association between postoperative bleeding and the HA application in patient #4 (Hemopatch®+ Floseal®) cannot be ruled out. However, in this last case (patient #4) the postoperative hemoglobin level was consistently greater than 13 g/dl.

Overall, the application of the HA Hemopatch® is technically feasible and safe during PN for suspicious renal lesions.

The main advantages of our study are the assessment of a large, single-surgeon case series accounting for a high internal validity as well as the evaluation of a real-life PN cohort.

Studies evaluating Hemopatch® in renal surgery are rare. This study is the follow-up analysis of our initial Hemopatch® study consisting of seven patients who underwent PN (period November 2013–June 2014) published in 2015 [13]. The median tumor sizes were similar in both cohorts (30.0 mm vs. 27.0 mm in past vs. current cohort, respectively). However, PADUA and RENAL nephrometry scores were higher, i.e., more complex renal lesions, in the current cohort (PADUA 6 vs. 7 and RENAL 4 vs. 6 in past vs. current cohort, respectively). In the past cohort, all lesions were single lesions compared to 8.9% multiple lesions in the current cohort. Taken together, the current follow-up cohort was more challenging and mirroring the surgeon's learning curve as well as a routine in Hemopatch® handling.

As of now, there are no phase III randomized controlled trials in humans comparing different types of HA during PN. There are only two randomized studies comparing HA vs. standard of care in humans.

Siemer et al. performed an open randomized prospective multicenter study comparing the HA TachoSil® (Takeda Pharmaceutical Co, Japan; Ethicon Inc., USA) vs. standard suturing in 185 patients who underwent PN [17]. In their investigation, the average time to hemostasis was approximately 5 min in the TachoSil® group vs. 10 min in the standard suture group. The authors concluded a superiority of TachoSil® compared to standard suturing with regard to intraoperative hemostasis [17].

Nativ et al. examined the effect of a newly designed fibrin pad (OMRIX Biopharmaceuticals Ltd., Israel; Ethicon Inc., USA) in a randomized phase I/II study [18]. They compared the fibrin pad with standard of care [suture, absorbable hemostat, and SURGICEL® (Johnson & Johnson Co., USA)]. Notably, as a result of a

Table 5 Comparison of complication rates of different PN studies

	Study details	Conversion	Blood loss	Transfusion rate	Clavien–Dindo
Current study	Open (11.1%) and laparoscopic (88.9%) PN with Hemopatch®; case series of $n = 45$	0% laparoscopic to open PN	Median 200 ml	8.9%	1: 2.2% 2: 4.4% 3: 13.3% 4–5: 0%
Imkamp et al. [13]	Laparoscopic PN with Hemopatch®; case series of $n = 7$	0% laparoscopic to open PN	Median 325 ml		No postoperative complication
Van Poppel et al. [4]	PN (49.5%) and RN (50.5%); prospective trial of $n = 541$		"Severe hemorrhage" PN 3.1%; blood loss < 500 ml PN 87.2%		3: PN 4.4%
Secin et al. [19]	Laparoscopic (98%) or robotic (2%) PN; retrospective study of $n = 1501$	3% PN to RN; 6% laparoscopic/ robotic to open PN	Median 200 ml	10%	1: 5.6% 2: 8.4% 3: 4.7% 4: 1.1% 5: 0%
Abu-Ghanem et al. [20]	Open (40.9%) or laparoscopic (59.1%) PN; $n = 657$			13.3%	
Abu-Ghanem et al. [20]	Subgroup sutures only vs. sutures and SURGICEL®; $n = 147$ vs. $n = 183$			4.1% vs. 19.1% ($p < 0.05$)	

PN partial nephrectomy, *RN* radical nephrectomy

severe bleeding in the fibrin pad group the study was suspended. Only seven of the planned 30 patients were enrolled [18].

One investigation by Lewis et al. compared Hemopatch® with Tabotamp® (Ethicon Inc., USA) in two animal models including heparinized rabbits and pigs mimicking vascular surgery (arterial bleeding) and general surgery (hepatic lesion) in patients with coagulopathy. In their analysis, Hemopatch® was superior to Tabotamp® [10].

Our perioperative metrics are in congruence with or superior to a recent multicenter study by Secin et al. reporting perioperative outcomes in a large series of laparoscopic (98%) or robotic (2%) PN ($n = 1501$) [19]. In Secin et al.'s cohort (vs. our cohort) the median operative time was 150 min (vs. 116 min), median intraoperative bleeding 200 ml (vs. 200 ml), median tumor diameter 27 mm (vs. 27 mm), transfusion rate 10% (vs. 8.9%), median RENAL score 6 (vs. 6), and conversion rate to open partial nephrectomy 6% (vs. 0%). Also, our overall complication rates were comparable to those of Secin et al. The complication rates were the following: Clavien I 5.6% (vs. 2.2%), Clavien II 8.4% (vs. 4.4%), Clavien III 4.7% (vs. 13.3%), Clavien IV 1.1% (vs. 0%), Clavien V 0% (0%) [19]. Notably,

that study is multicenter (17 centers). The surgical technique as well as whether or not a HA was utilized intraoperatively is not described in the study [19].

There is also a controversial study about the usage of HA in PN by Abu-Ghanem et al. [20]. The authors investigated 657 patients who underwent PN and evaluated the impact of different sealants and SURGICEL® on complications. In the total cohort the transfusion rate was 13.3% while urinary leakage occurred in 2.6% of the patients. When comparing sutures only (n = 147 patients) vs. sutures and SURGICEL® (n = 183 patients) the authors noticed a higher transfusion und urinary leakage rate (19.1% vs. 4.1% and 4.9% vs. 0.7%, respectively, both $p < 0.05$) in the SURGICEL® group. However, tumors in the SURGICEL® group were larger (3.83 cm vs. 3.01 cm, $p < 0.05$) and more often centrally located (43.2% vs. 23.8%, $p < 0.05$). There was no difference regarding postoperative bleeding (defined as hematuria or flank hematoma) [20]. Abu-Ghanem et al. also evaluated the effect of the combination of sutures, sealant, and SURGICEL® (n = 301). This combination did not result in more favorable outcomes with regard to transfusion rate, urinary leakage rate, postoperative hematuria, or flank hematomas [20]. As the addition of HAs does not seem to reduce complications, the authors conclude that an accurate suturing of the resection zone may be sufficient to control bleeding. Importantly, this study is not a prospective randomized study either [20].

Table 5 compares the complication rates of the current study, our former case series, the prospective study by Van Poppel et al., the multicenter study by Secin et al., and the comparative study by Abu-Ghanem et al. [4, 13, 19, 20].

There are some limitations of our analysis. Notably, this patient cohort does not include all consecutive patients who underwent PN at the Medical School of Hannover between December 2013 and March 2018. Retrospective inclusion of a patient in this study was based on the surgeon's individual choice of HA. Thus, there is selection bias. Furthermore, comedications such as antiplatelet or anticoagulant treatment were not included. There was no comparison with other HAs or non-HA surgeries. The surgical approach was not standardized with regard to suturing techniques for hemostasis. The case number is low because of the single-surgeon character of the study.

CONCLUSIONS

In this study we report our deepened experiences with the HA Hemopatch® in PN. The feasibility and reliability of the HA Hemopatch® that were demonstrated in our initial study [13] were further confirmed in a larger and more complex PN cohort. There is a need for prospective randomized trials comparing different types of HA with regard to perioperative complication rates.

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Compliance with Ethics Guidelines. Hemopatch® is certified for use in the territory of the European Union; therefore, approval from the institutional board was not required for its application. Furthermore, this study was granted exemption from requiring local ethics approval (Medical School Hannover) because of its retrospective design and because informed was consent obtained beforehand from all patients. The study was performed in accordance with the Helsinki Declaration of 1964, and its later amendments.

Data Availability. The datasets generated during and/or analyzed during the current study are notpublicly available because of privacy or ethical restrictions.

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