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Intravesical tranexamic acid for patients requiring continuous bladder irrigation in the ED: A non-randomized feasibility study

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Abstract

Objectives: Tranexamic acid is a well studied clot stabilizer that may offer benefits when used intravesically prior to continuous bladder irrigation. This study determined the feasibility of conducting a randomized controlled trial using tranexamic acid intravesically in participants who present to the emergency department. The study goals were to recruit 20 participants within a six-month time frame and have an 80% recruitment rate.

Methods: Potential participants were identified at triage if they presented with a complaint of hematuria or urinary retention and were over the age of 18. Informed consent was obtained if the participant needed continuous bladder irrigation and met inclusion or exclusion criteria. If consented, tranexamic acid was instilled intravesically at the start of continuous bladder irrigation treatment and the patient was followed until their continuous bladder irrigation treatment was complete.

Results: A total of 14 (out of 18) participants were recruited over eight months. The mean age of participants was 74.5 (SD = 7.4) years, with only one of the 14 participants identifying as female. For resource management, the study was designed to include support from an on-call nurse who was available at any time to review potential participant eligibility, complete study intervention, and collect study data. The on-call nurse was called seven out of 14 times and came into hospital one time. Eight participants did not require hospital admission after the tranexamic acid intervention. The mean length of hospital stay for participants was 4.6 (SD = 2.7) days. The mean emergency department length of stay was 8.1 (SD = 4.9) hours. There were no reported adverse events.

Conclusion: The recruitment rate of 78% (*n* = 14) suggested that the study had an acceptable design to participants, but we were unable to meet our goal of recruiting 20 participants over six months. No adverse events were found using our study protocol.

Keywords: tranexamic acid, hematuria, urinary retention, continuous bladder irrigation

Introduction

Background

Urinary retention due to hematuria is a common emergency department (ED) presentation that often requires continuous bladder irrigation (CBI; Canadian Institute for Health Information, 2019; Groninger & Phillips, 2012; Germann & Holmes, 2018). CBI is a labour-intensive process that requires a high level of nursing resources, is associated with lengthy hospital stays, and is an invasive and painful procedure for the participant (Canadian Institute, 2019; Ng, 2001). CBI is often required in participants with clot retention caused by post-operative prostate complications or bladder and prostate malignancy (Groninger & Phillips, 2012). CBI catheter blockage by blood clots often happens multiple times during treatment, resulting in painful urinary retention and requiring labour-intensive manual clot irrigation by nursing staff (Ng, 2001). Participants receiving CBI often require a disproportionate amount of care and attention, leaving fewer resources for other ED patients.

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Importance

There has been recent interest in adding antifibrinolytics, such as tranexamic acid (TXA), to the standard CBI treatment protocol, due to the fact that the bladder and prostate are enzymatically active in clot breakdown and prone to hematuria and clot retention (Mina & Garcia-Perdomo, 2018; Pavlovic et al., 2012). Clots in the bladder lead to urinary retention and require manual irrigation from nursing staff which results in CBI patients requiring a high nursing resource utilization. Intravenous TXA has been studied looking at effectiveness in decreasing bleeding during prostate surgery (Mina & Garcia-Perdomo, 2018) but to our knowledge, there has only been one randomized controlled trial that studied TXA intravesically for control of hematuria and clot retention (Moharamzadeh et al., 2017). This study demonstrated a decrease in total irrigation fluid and a faster time to urine hemoglobin clearing when compared to current standard of care without the use of TXA (Moharamzadeh et al., 2017). Although these results are encouraging, the outcomes did not specifically address participant and staff burden. Our team is interested in exploring the effect of TXA when administered intravesically prior to initiation of CBI to explore improvement of participant outcomes.

Study objectives

We conducted a feasibility study to inform the development of a future full-scale randomized controlled trial looking at the effect of intravesical TXA on participants requiring CBI in the ED. Specifically, we studied the accessibility and retention of potential participants, site appropriateness, study intervention adherence, resources, clinician engagement, and preliminary safety data.

Methods

Study design and time period

This non-randomized feasibility study looked at the possibility of a full-scale randomized controlled trial by examining the effects of intravesical TXA in the ED for participants with hematuria and clot retention requiring CBI. The goal was to recruit 20 participants over six months. The study was extended for an additional two months due to difficulties in recruitment and staffing during the COVID-19 pandemic. The study was conducted at two Canadian EDs that have significant overlap with physician and nursing staff. One ED is a large academic centre and the other is a community hospital. The manuscript complies with the CONSORT extension guidelines for "Pilot and Feasibility Trials" (Eldridge et al., 2010).

Team

The study had a total of 14 registerd nurses (RNs) that were trained on the details of consent, study protocol, intervention, and data gathering. The study RNs made up the cohort of on-call RNs available to support the study. These RNs held regular in-services in the ED leading up to the study, to train other nurses of the study details. In-services were also held with inpatient unit nurses as well.

Selection of participants

Participants were recruited via convenience sampling when presenting to the ED triage with a chief complaint of either hematuria or urinary retention. There was 24-hour coverage with an on-call study nurse who the triage team could call if any potential participants were identified and who would come to the ED to support the study and intervention.

Inclusion criteria were adult participants 18 years of age or older, ability to consent to study, and presenting complaint of urinary retention caused by hematuria or clot retention that required CBI. Participants were excluded if they were pregnant, breastfeeding, used anticoagulants or hormonal contraception, had known coagulopathy, urinary tract infection, pyelonephritis, active angina, acquired disturbances to colour vision, known hypersensitivity to TXA, known renal failure, polycystic kidney disease, known or history of thrombosis or thromboembolism, and cognitive impairment rendering them unable to provide informed consent and not having available substitute decision-maker present.

Consent was obtained by either a RN or an emergency physician that had undergone study-specific informed consent training. Data were collected until the CBI treatment was completed, and therefore some data collection took place on inpatient units. Data collections were done by RNs (either the primary RN or a dedicated study RN) who had been trained by study staff and followed the data collection sheets.

Intervention

A 22 or 24Fr three-way Foley catheter was inserted using standard nursing protocols. The RN manually irrigated the bladder to remove clots upon catheter insertion. One gram of TXA was mixed with 50 ml of normal saline, then directly instilled into the bladder through the catheter. This dose was chosen as it has been used extensively in other applications with a good safety profile (Roberts et al., 2013; Dewan et al., 2012; Ker et al., 2013). The catheter then was clamped, allowing the medication to be instilled for 15 minutes. After 15 minutes, the catheter was unclamped, and CBI treatment was carried out as per nursing procedures.

Outcome measures and sample size

The study's primary objective was to determine the acceptability of the study procedures to participants. This was measured by a ratio of eligible participants who consented to the intervention and post-study interviews to those who were eligible for the study but declined the intervention. An acceptable recruitment rate was determined to be 80%. Site appropriateness for obtaining eligible participants was a secondary objective measured by the ability to recruit 20 participants over six months between both sites. As there is little literature to guide our design, a total of 20 participants was selected for our sample size as it was felt that would generate sufficient data to answer the study questions. We limited the study recruitment to a six-month time period to assess the appropriateness of study hospital site in attaining eligible study participants in a reasonable time frame.

Other secondary objectives included the examination of the study protocol process with time from triage to intervention, and equipment used. Staff engagement and resource use was assessed via post-study interviews. We also measured the time from participant identification at triage to consenting and between consenting to study intervention to explore if the study protocol may delay participant care time. We collected participant demographic information and preliminary safety data (adverse events) to inform future trials.

Data analysis

Quantitative data were summarized using means and standard deviations, frequencies and percentages as appropriate. Participant and RN semi-structured interviews were done by a study RN or a research assistant by using an interview guide developed by the study team. Interviews were analyzed for themes and coded.

Ethics approval was granted by the Fraser Health Research Ethics Board and the University of British Columbia Clinical Research Ethics Board under Record REB Number FHREB 2020-085 and H20-02812, respectively. This study was prospectively registered April 14, 2020, under "Intravesical Antifibrinolytic for Patients with Hematuria and Clot Retention" (registration number: NCT04555343) with the National Clinical Trial Registry and approval to use TXA intravesically from Health Canada was obtained.

Results

Quantitative data

Screening and enrollment took place between February 1st and Aug 31st, 2021. A total of 18 participants met the inclusion criteria and 14 participants agreed to participate in the study. One participant who consented did not receive the TXA intervention due to complications with catheter insertion. Table 1 displays the baseline characteristics of the study participants. The median age of participants was 72 years with only one of the 14 participants identifying as female. 11 participants presenting with a chief complaint of hematuria with three participants presenting with a co-complaint of both hematuria and urinary retention. Eight participants had no relevant surgical history with four reporting previous transurethral resection of the prostate. One participant had a previous prostate biopsy and one had a prostatectomy. Benign prostate hyperplasia was the most common reported relevant medical history (five participants) with four participants reporting having bladder cancer, two with prostate cancer, one with previous bladder radiation and one with prostatitis.

Twenty-three people were screened for eligibility with 18 meeting criteria. 14 successfully consented and were recruited, which is a 78% recruitment rate. No participants that received the TXA intervention reported any adverse events.

Table 2 displays details related to the study protocol. The mean time between participants presenting at triage to consenting to participate was 146 (SD = 91) minutes. The mean time between consenting to TXA administration was 47 (SD = 44) minutes. The mean time between TXA administration and the catheter being unclamped was 14 (SD = 3) min. Eight participants received a 22-Fr Foley.

Table 3 displays resource use data. Five participants required no subsequent manual irrigation, four participants required one to six subsequent irrigations, and five participants had no data recorded for this outcome. Eleven participants did not require CBI to be restarted once it had been discontinued. The on-call nurse was called seven out of 14 times and came into hospital to support the study one time. Four times the on-call nurse was already in hospital and helped with the study while on shift. When the on-call nurse was not called, RNs trained in study protocol completed the intervention. Eight participants did not require hospital admission after the TXA intervention. The mean length of hospital stay for participants was 4.6 (SD = 2.7) days. The mean ED length of stay was 8.1 (SD = 4.9) hours.

Table 1

Demographic and Clinical Characteristics

Variable	Response	SD
Age (years)		
Mean	74.50	1.58
Sex (*n*, %)		
Male	13	92.8
Female	1	7.2
Presenting complaint (*n*, %)		
Hematuria	11	78.6
Hematuria and urinary retention	3	21.4
Length of pre-existing symptoms (*n*, %)		
Less than a week	11	78.6
Less than a month	2	14.3
More than one month	1	7.1
Medical History (*n*, %)		
Bladder cancer	4	28.6
Bladder radiation	1	7.1
Benign prostate hyperplasia	5	35.7
Prostate cancer	2	14.3
Prostatitis	1	7.1
Surgical history (*n*, %)		
None	8	57.1
Prostate biopsy	1	7.1
Prostatectomy	1	7.1
Transurethral resection of prostate	4	28.6

Note. SD = standard deviation.

Semi-structured interviews

Below are the major themes and quotes highlighted in the post-intervention follow up interviews of the study participants and the involved RNs. See Appendix for interview questions.

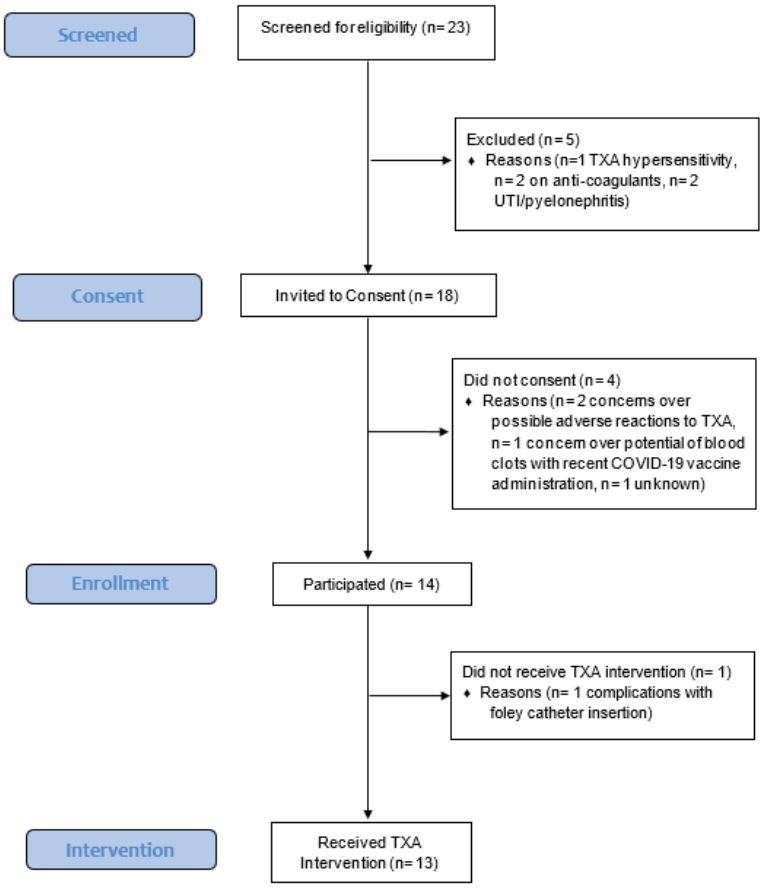
Discussion

Interpretation of findings

As this was a feasibility study to prepare for a full-scale RCT, our primary objective was to determine site appropriateness and intervention acceptability to participants. We targeted obtaining twenty participants over a six-month period and an 80% recruitment rate. Due to complications of the COVID-19 pandemic, we extended our study and recruited participants over eight

Figure 1

CONSORT Flow Diagram



Note. TXA = tranexamic acid.

Table 2

Study Procedures

Procedural variables	N = 14	SD
Time to Consent (minutes) mean (SD)	146	91
Time to TXA administration (minutes) mean (SD)	47	44
Duration of TXA application (minutes) mean (SD)	14	3
Initial irrigation performed (*n*, %)		
Yes	12	85.7
No	2	14.3
Foley Size		
22-Fr	8	57

Note. SD = standard deviation; TXA = tranexamic acid.

Table 3

Resource Use

Resource use variables	Response	SD
ED length of stay, *n* = 14 (hours) mean (SD)	8.1	4.9
Hospital length of stay, *n* = 6 (days) mean (SD)	4.6	2.7
Admission to hospital (*n*, %)		
Yes	6	43
No	8	57
Manual irrigation		
Not recorded	5	35.7
No	5	35.7
Yes	4	28.6
CBI re-start		
Not recorded	1	7.1
No	11	78.6
Yes	2	14.3

Note. SD = standard deviation; ED = emergency department; CBI = continuous bladder irrigation.

Table 4

Semi-structured Nurse and Participant Interviews

Participants		
Theme	**Description**	**Quotations**
Experience with informed consent process	Overall participants felt that the consenting process was clear and had the right amount of information. Although the participants understood the importance of informed consent and felt that they understood the information, several felt as though the process prolonged their discomfort related to urinary retention.	*"Didn't find it bad at all, not time consuming at all, someone came and asked me, and I said yes."* *"No, if I was a stickler for details and you had to sit and read through all that while experiencing trauma, people may say 'I just want to get treated', I read it."* *"It was fast- the situation at the time- I didn't want to read all of it. I couldn't even think about it to be honest. I sent it to my wife and texted her, and we decided it was safe."* *"No problem- it felt like a normal consenting process."* *"Enough information, not too much. The doctor explained everything".*
Study experience	Participants all felt overall satisfied with their participation in the study. A few expressed that they felt well cared for by the physician and nursing team. None expressed any additional discomfort or perceived adverse reactions related to the study process, intervention, or TXA. One participant who had experienced ten previous CBIs commented that the study used led to less frequent manual irrigations and that they believed the bleeding cleared faster than other experiences.	*"The doctor did a really good job, hopefully this trial helps make things better."* *"This time I had two blockages, and the irrigation was really simple."* *"No discomfort from the drug, I was already in pain because of the blood clots."* *"The nurse that was with me the whole time was marvelous. She was in all the time, making sure I wasn't in pain".*
Nurses		
Theme	**Description**	**Quotations**
Protocol and intervention	No issues were identified with the protocol or intervention. All study RNs found the instructions clear and easy to follow.	*"I thought it was quite clear. I didn't find it was difficult. Simple. Easy to understand."* *"That was clearly laid out. That was good."*
Supplies	Supplies were regularly stocked items for CBI treatment, but it took some additional time to gather the supplies specific to the TXA intervention. Initially equipment kits were pre-packaged, but as the study progressed the kits were discontinued as it took more time to prepare them in advance.	*"So then, towards the end, we just had to collect all the supplies so there's like a little but more of a hassle, but it was still fine."*
Data collection logistics	Regular RNs found the data sheets were clear and easy to follow. The study-specific nurses that followed their participants, once they were admitted, noticed that the nurses outside the ED did not fill out many parts of their forms (this was confirmed during data entry and required electronic medical record access to fill in missing data).	*"I don't think we ever got those forms back from the upstairs wards. They got lost and I don't know if the nurses were actually completing them."*

continued…

Identification and consenting	Most nurses felt the identification and consenting process was clear. Most participants that were identified but excluded were due to anti-coagulant use. There was some confusion around defining an anticoagulant use as some nurses considered anti-platelets as anticoagulants. Nurses felt it was easy to identify and get consent from participants when the department wasn't too busy but struggled when volumes were too high.	*"I thought that when we weren't slammed, we did a really good job of identifying. And sometimes even when we were slammed, we still did a good job identifying."* *"The eligibility criteria was kind of difficult, like a lot of these patients will have hematuria but a lot of them I think blood thinners are a big issue."*
On-call schedule	Overall, RNs liked the idea of an on-call schedule but were very hesitant to activate it and there were significant gaps in the schedule as the study progressed. Many RNs commented that it was easier to do the intervention if they happened to be on shift rather than call the on-call nurse, even though it increased their workload significantly. As the study progressed into summer months and throughout the pandemic, RNs were working significantly more shifts with high workload demands and were unable to pick up on-call study shifts.	*"It was just easier for me to do it."* *"Ya it was a lot hard than we thought (on-call schedule), it was hard to come into work."* *"Normally we don't work on call in the ED, no one's ever done that before. I don't think it was worth it personally. The money isn't worth it."*
Workload	CBI is already a very labour-intensive treatment; the addition of the data sheets and intervention made it even more challenging. RNs had to complete the data sheet after their shift or during their breaks. Other RNs had to pick up extra work and participant care, while study RNs were doing the intervention or data sheets.	*"CBIs in general are just very time consuming. So, I found, particularly when we first started doing it, it took a lot of extra time just to make sure that we were doing everything properly."* *"It's like way too much. You're like running and you still have your own assignment and then you're also trying to pay attention to this patient who's uncomfortable, possibly in pain and needs frequent checks. So, it like really seems unfair to both the patient and your patient load."* *"I think you'd have to do it (data sheets) on a break. Or like when you're off work."*
COVID-19 pandemic-specific challenges	One common theme was that this study was very challenging as it was run during the COVID-19 pandemic. RNs expressed concerned of being burnt out due to pandemic challenges, which lowered health care worker study engagement and increased workload during an already high volume and complex ED landscape. RNs felt as though participant recruitment suffered due to the pandemic secondary to cancellation of schedule surgeries, fear of blood clot during initial COVID-19 vaccine roll out, and nursing shortages.	*"I had three patients that didn't want to do the study because of the association of the vaccines."* *"I think everyone feels pretty tired and burnt out at work and it's just like any little extra is too much."* *"Just the timing was bad with the pandemic and now the nursing shortage."*

months. We met our 80% retention goal, but were only able to recruit 14 participants. To note, studies using TXA intravesically previously had a 74% recruitment rate (Moharamzadeh et al., 2017). This study was conducted during a time when there were concerns over COVID-19 vaccines being linked to blood clots. Because the theoretical risk of blood clots being linked to the TXA intervention was included in our informed consent, some participants declined to participate. When speaking with nursing team members, many mentioned that due to increased workloads during the COVID-19 pandemic, there were participants eligible requiring CBI that were not screened to be a part of this study. Also, because transurethral prostate resection is an elective surgery, the pandemic limited the number of post-op transurethral prostate resection complications requiring CBI and likely reduced our participant pool.

There was a significant time from when participants presented to triage and when they consented to participate (146 minutes). This may be reflective of the busy nature of the ED but also may signify a delay in care due to study set up. Also, time from consent to TXA administration was approximately 47 minutes and likely requires consideration when moving forward with an RCT so that participant discomfort while in retention is minimized.

Although this study is looking at the feasibility of a randomized control trial, preliminary data on TXA with CBI was collected. There were participants that required no further manual irrigation and some that did not require an admission to the hospital after TXA intervention. Further studies need to be done to assess if TXA does make a statistical difference in resource utilization, hospital admissions, and length of stay.

From a participant perspective, participants shared that the delay of CBI initiation for the study consent and intervention resulted in prolonged pain or discomfort secondary to urinary retention. While this may have impacted our recruitment, it is also concerning that our intervention may have negatively impacted participant care. To mitigate this, we could have initiated CBI as per standard protocol and then offered the TXA intervention within a defined timeframe to ensure participant comfort without compromising the effects of the intervention. For future studies, participants will receive CBI initially and be asked for their consent for study participation after retention is relieved.

Nursing availability was also highlighted as a concern in our follow-up interviews. When planning the study, nursing team members agreed to a rotating on-call schedule for 24hr coverage. The on-call nurse was only called seven out of 14 times. Nurses shared that in reality, they were unprepared to be on-call and the infrequency of calls resulted in lack of interest or them wanting to pick up other nursing shifts to ensure financial compensation for their work. They often found it easier to find someone on shift as opposed to calling the on-call nurse. When planning future studies, our team will have to move forward with working with an ED that has an on-site research assistant to ensure there is always coverage and potential participants are not missed.

Strengths and limitations

There were no adverse events noted and the study protocol was followed appropriately. Although this is not a comparison trial, we find it hopeful that TXA will have a positive impact on participant care as more than half of the participants did not require hospital admission following TXA intervention.

Undertaking this study during the COVID-19 pandemic was a significant limitation. The increased workload and complications around vaccine risk may have impacted the ability to recruit participants. Some data was not collected by study RNs, limiting the ability to analyze the data. Also due to the pandemic, there was limited time to dedicate to study consent and process, which impacted recruitment. The study also was limited to two EDs from similar demographic and geographic areas and findings would be transferable to similar departments. Specifically, many participants had a history of bladder cancer which may not reflect other ED populations. The health authority does not capture data outlining all participants who received CBI and for what reason. This limited our ability to have an accurate participant capture/recruitment rate.

The goal of 80% recruitment may have been higher than realistically achievable. For future studies, a lower recruitment rate with a longer period of study would be helpful in gathering enough participants.

Conclusion

This study highlighted important factors to consider when preparing for a full-scale randomized control trial. The effects of the COVID-19 pandemic on recruitment and nursing workload cannot be underestimated and timing will be considered when moving forward. We will ensure coverage for a research assistant to ensure appropriate identification, screening and support for the intervention and logistical aspect of the study. We will modify the study protocol to mitigate the risk of prolonging participant discomfort by irrigating and initiating CBI prior to consent and TXA administration. Our future trial will be a double blinded randomized controlled trial with two arms: placebo or TXA intervention. This will require additional resources including research assistants to support recruitment, informed consent, and nursing staff.

Implications for emergency nursing practice

1. Urinary retention secondary to blood clots often requires CBI which contributes to prolonged stays and high resource use.
2. TXA is an acceptable addition to CBI and may decrease nursing resource utilization, while improving participant outcomes.
3. This study demonstrated the need for a well designed and executed RCT to gather evidence about its efficacy.

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Conflicts of Interest

Mr. Ross Soros (patient partner, co-author) is the father of Dr. Kelly Soros (co-author). Mr. Ross Soros, patient partner, has received financial compensation for travel to meetings and his time. Registered nurses that were on call to complete the study intervention or completed the intervention before/after a shift received compensation. Several authors received financial compensation for project set up, interviewing, and administrative work. None other reported amongst the authors and no authors received any financial support for data analysis or manuscript writing.

Contributions of the authorship team & CRedIT author statement

Soros, Kelly: *trial design, research funding, Health Canada application, trial supervision and data collection, study protocol, data analysis, data entry, manuscript draft and revisions.* ***Abdalvand, Ali:*** *trial design, research funding, data collection and trial supervision, study protocol design, research intervention, manuscript draft.* ***Soros, Ross:*** *intervention design, manuscript draft.* ***Ivkov, Vesna:*** *research funding, Health Canada application, data entry, manuscript draft.* ***Suri, Kris:*** *data entry, patient interviews, data entry, manuscript draft.* ***Marenghi, Helen; Darby, Abigail; Bucovaz, Angeli; Chan, Wendy; Donoso, Isadora; Duggan, Karin; LeComte, Megan; Morrison, Samantha; Kempling, Esther; Tisseur, Ashley:*** *study protocol design, research interventions, staff in-services, manuscript draft.*

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Appendix

Semi-Structured Interview Templates

Nursing

Date of Interview: _____

Name of Nurse: _____

Any comments on the initial identification or consenting process?

Any comments on the TXA intervention protocol?

Was the protocol clearly laid out?

Were supplies easy to find?

Any comments on the on-call nurse?

Did you call the nurse?

If you did, were they helpful?

If you did not call the nurse, reasons why?

Any comments on the data collection sheets?

Any comments on how this study affected your workload?

Comments on how to engage care providers in this study?

Any other comments?

Patient

Interview Date: _____

Patient Study ID: _____

How many times have you had CBI treatment in total?

Why did you need CBI treatment?

If you have previously had CBI treatment before this study, did you notice any difference with the TXA intervention?

Any comments on the consenting process?

Any discomfort or pain related to the TXA intervention?

What is your overall experience with the intervention?

What is your overall satisfaction with the intervention?

Any comments on the intervention?

Anything else you would like the research team to know?