

Contemporary Management of Right Upper Quadrant Gunshot Wounds

Background and Significance

As a result of the understanding of both the short and long term sequela of non-therapeutic laparotomy, the management of penetrating abdominal wounds has evolved significantly from a time of mandatory laparotomy to the contemporary practice of selective non-operative management.¹⁻⁴ Non-operative management of select penetrating abdominal injuries in hemodynamically normal patients without peritonitis is feasible and is currently endorsed by guidelines from both the Eastern Association for the Surgery of Trauma (EAST) and Western Trauma Association (WTA).⁵⁻¹¹ These guidelines recommend that in the absence of hemodynamic instability and peritonitis patients with right upper quadrant (RUQ), including right thoracoabdominal (TA), penetrating injuries be considered for non-operative management. While most studies underlying these recommendations have primarily focused on the feasibility and failure rates of selective non-operative management of these injuries¹², few have evaluated the need for additional abdominal and thoracic interventions between those managed non-operatively compared to those managed initially with operative intervention. A recent retrospective study of primarily blunt grade III and above liver injuries found that operative management was associated with an increased need for unplanned procedures on bivariate analysis, but this association disappeared on logistic regression.¹³ Interestingly, firearm injury was independently associated with an increased need for unplanned interventions. There has also been increasing interest in the evaluation of long term outcomes in patients who sustain penetrating injuries¹⁴, and, to our knowledge, no previous studies have specifically examined the long term outcomes in patients with penetrating RUQ wounds.

Primary Aims

In this multicenter, prospective observation study, our primary aim is to:

- 1) Compare short and long-term outcomes in patients with RUQ gunshot wounds managed operatively to those initially managed non-operatively. Long term outcomes include 6 month physical and mental functioning as well as work status.

Secondary Aims

- 1) To describe the current practice patterns for the management of RUQ gunshot wounds in hemodynamically normal patients without peritonitis
- 2) To describe the current failure rate of selective non-operative management of RUQ gunshot wounds
- 3) To identify factors associated with the need for unplanned interventions in this population

We feel that our study is important in that 1) contemporary management and outcomes of RUQ gunshot wounds have not recently been described in a multi-institutional prospective study in the context of management strategies that (in our experience) vary across surgeons and institutions, and 2) to our knowledge, the long term outcomes of patients with gunshot wounds to the RUQ region managed operatively and non-operatively have not been described.

Thus far, we have verbal commitment for study participation from four busy trauma centers (University of Pennsylvania, University of Rochester, University of Texas Southwestern (Parkland), University of Pittsburgh Medical Center), and anticipate that more centers will be interested in participating.

Hypothesis

Selective non-operative management of isolated RUQ gunshot injuries without hemodynamic compromise or peritonitis is feasible and is associated with decreased unplanned intervention.

Inclusion Criteria (see Figure 1)

- **Isolated** RUQ wound(s) identified during initial trauma evaluation as defined below:
 - Isolated RUQ (lateral to xiphoid, superior to umbilicus, anterior to anterior axillary line).
 - Isolated posterior "RUQ"¹⁵ (between tip of scapula and posterior superior iliac spine in the cranial-caudal direction and gluteal cleft and posterior axillary line in the medial to lateral direction).
- Age \geq 18
- Hemodynamically normal (heart rate, HR, \leq 120 beats/min and systolic blood pressure, SBP, \geq 100 mmHg) during initial resuscitation in emergency department
- No diffuse peritonitis on abdominal exam

Exclusion Criteria

- Age <18
- Prisoner
- Pregnancy
- Hemodynamic instability (HR > 120 beats/min and/or SBP <100 mmHg) during initial resuscitation in emergency department
- Diffuse peritonitis on abdominal exam
- *Any* gunshot wound *not* isolated to anterior or posterior RUQ as described above. Note that right flank wounds are excluded by above definitions
- Need for emergency department thoracotomy
- Death within 24 hours of admission

Therapeutic interventions

As this is a prospective observational study, patients will be managed according to surgeon discretion, and no therapeutic interventions will be recommended as part of the study protocol.

Primary Outcome

Need for any unplanned intervention, defined as *any* of the following procedures > 48 hours post admission (hospital day 3 or after) (similar criteria used in recent study¹³): Endoscopic retrograde cholangiopancreatography (ERCP), interventional radiology intra-abdominal drain placement, angiography +/- embolization, laparotomy/laparoscopy, ureteral stent placement, percutaneous nephrostomy tube placement, thoracotomy, video assisted thoracoscopic surgery (VATS), open or percutaneous chest tube placement. A planned return to the operating room for a patient with an open abdomen will not be considered an unplanned operation unless the laparotomy occurs after the abdomen is closed.

Secondary Outcomes (see data collection tool for additional information)

Failure of non-operative management (defined as need for laparotomy during index admission after initial trial of non-operative management)

Total number of unplanned interventions

Hospital length of stay (LOS)

Intensive care unit (ICU) LOS

30 day hospital re-admission

In-hospital mortality

Intrathoracic complications (biliary-pleural fistula, retained hemothorax, empyema, persistent air leak (>5 days))

Intra-abdominal complications (bile leak, liver necrosis, intra-abdominal abscess, delayed hemorrhage, pseudoaneurysm development, missed bowel injury)

Total number of blood products transfused during hospitalization

Venous thromboembolism (DVT/PE)

Discharge disposition (home, long-term acute care, acute rehab facility, skilled nursing facility)

Total number chest/abdominal/pelvis CT scans/MRI studies during index admission

Need for chest tube and/or intra-abdominal drain at discharge

6-month outcomes (PROMIS–29 Profile v2.1 metric, attached, as well as 6-month re-admissions, ED visits, and work status)

Variables to be collected (see data collection tool for details)

Demographic variables

Initial emergency department (ED) physiology

Initial ED laboratory values

Initial and 24 hour blood product usage

Past medical history

Injury characteristics

Initial ED management variables

Post-ED management variables (including operative and post-operative management if applicable)

Short and long-term outcome variables

Data Collection and Statistical Analysis

Standardized data will be collected for each patient (see data collection tool). Descriptive statistics will be used to describe current management strategies. Outcomes will be compared between those who underwent immediate operative intervention vs. successful selective non-operative management, between those who underwent immediate operative management vs. those who underwent operative management (laparotomy) after failing selective non-operative management, and between those who underwent successful non-operative management vs. failed non-operative management.

The crux of this study is to compare injuries that were managed non-operatively to those managed operatively *but could have potentially been managed without an operation* in order to minimize confounding by indication. **Therefore, in the final analysis, we will be comparing outcomes only in patients with isolated liver/right kidney/right adrenal injuries (or no injuries) identified on either initial CT scan or operative intervention when applicable (see Figure 1).** Right sided chest wall, right lung, and right diaphragm injuries are not excluded. We will also compare operative vs. non-operative

management in the *a-prior* assigned subgroup of right sided TA injuries (injuries that involve right chest wall/lung/diaphragm in addition to right upper quadrant solid organs).

Student's t-test will be used for parametric data and Mann Whitney-U test for non-parametric data. χ^2 /Fishers exact tests will be used to compare differences between categorical variables when appropriate. Univariate and multivariable logistic regression will be used to determine factors associated with need for unplanned procedures (all variables with a p value <0.2 on univariate analysis will be entered into a multivariable logistic regression analysis). Statistical significance will be set at 0.05. We do have availability of statisticians at the primary site.

A recent study evaluating operative vs. selective non-operative management of blunt and penetrating grade III and above liver injuries found that 26% of patients with penetrating injuries required an unplanned procedure, compared to 15 % overall. Overall, 24% of those managed operatively required delayed intervention compared with 8% of those managed non-operatively. Although our population is obviously different, using these findings, a sample of 74 total patients would be required to show this statistical difference with 80% power at an alpha of 0.05.

We recognize that including 6 month long-term outcomes data using the PROMIS–29 Profile v2.1 metric will add additional work to the project in that these patients will need to be contacted by telephone after hospital discharge. However, we feel that this is important information to obtain when evaluating operative vs. non-operative management. In addition, we expect that any individual center will have 10-20 patients over the study period, and we hope that this will not add a significant amount of work for each center. A standardized script will be provided in order to carry out 6-month telephone interviews. Please see reference 14 for an example of how PROMIS instruments have been used in the penetrating trauma population.

With respect to timeline, we anticipate 1.5 years of data collection, including 1 year of prospectively identifying patients who meet inclusion criteria followed by an additional 6 months to allow evaluation of 6 month outcomes without accruing new patients.

All data plan will be entered into a password-protected Redcap database (Vanderbilt University, Nashville, TN) utilizing branching logic for ease of use after appropriate data share agreements are completed. Prior to data share agreements and Redcap usage, centers will be provided with a data collection sheet for initial data collection.

Consent Procedures

Written informed consent will be required for subjects to complete the baseline and 6-month PROMIS metric and long-term outcomes questions. A standardized consent form will be provided that can be altered based on institutional requirements.

Risk/Benefit Analysis

The main risk associated with this type of prospective observational study is a data/confidentiality breach which will be mitigated through appropriate data handling as outlined in each individual IRB application. This risk is thought to be minimal. Benefits include a better understanding of current practice patterns for the management of RUQ gunshot injuries as well as those associated with

operative vs. non-operative intervention with the ultimate goal of improving the short and long term care of this patient population.

References

1. Leppaniemi A, Salo J, Haapiainen R. Complications of negative laparotomy for truncal stab wounds. *J Trauma*. 1995;38(1):54-8.
2. Li T, Robertson-More C, Maclean AR, et. al. Bowel obstructions and incisional hernias following trauma laparotomy and the nonoperative therapy of solid organ injuries: A retrospective population-based analysis. *J Trauma Acute Care Surg*. 2015;79(3):386-92.
3. Morrison JE, Wisner DH, Bodai BI. Complications after negative laparotomy for trauma: long-term follow-up in a health maintenance organization. *J Trauma*. 1996;41(3):509-13.
4. Hasaniya N, Demetriades D, Stephens A, et. al. Early morbidity and mortality of non-therapeutic operations for penetrating trauma. *Am Surg*. 1994;60(10):744-7.
5. Martin MJ, Brown CVR, Shatz DV, et. al. Evaluation and management of abdominal gunshot wounds: A Western Trauma Association critical decisions algorithm. *J Trauma Acute Care Surg*. 2019;87(5):1220-27.
6. Martin MJ, Brown CVR, Shatz DV, et. al. Evaluation and management of abdominal stab wounds: A Western Trauma Association critical decisions algorithm. *J Trauma Acute Care Surg*. 2018;85:1007-15.
7. McDonald AA, Robinson BRH, Alarcon L, et. al. Evaluation and management of traumatic diaphragmatic injuries: A Practice Management Guideline from the Eastern Association for the Surgery of Trauma. *J Trauma Acute Care Surg*. 2018;85(1):198-207.
8. Reed BL, Patel NJ, McDonald AA, et. al. Selective nonoperative management of abdominal gunshot wounds with isolated solid organ injury. *Am J Surg*. 2017;213(3):583-85.
9. Renz BM and Feliciano DV. Gunshot wounds to the right thoracoabdomen: a prospective study of nonoperative management. *J Trauma*. 1994;37(5):737-44.
10. Como JJ, Bokhari F, Chiu WC, et. al. Practice Management Guidelines for selective nonoperative management of penetrating abdominal trauma. *J Trauma*. 2010;68(3):721-33.
11. Demetriades D, Hadjizacharia P, Constantinou C, et. al. Selective nonoperative management of penetrating abdominal solid organ injuries. *Ann Surg*. 2006;244(4):620-8.
12. Al Rawahi AN, Al Hinai FA, Boyd JM, et. al. Outcomes of selective nonoperative management of civilian abdominal gunshot wounds: a systematic review and meta-analysis. *World J Emerg Surg*. 2018;13.
13. Edalatpour A, Young BT, Brown LR, et. al. Grade of injury, not initial management, is associated with unplanned interventions in liver injury. *Injury*. 2020;51:1301-1305.

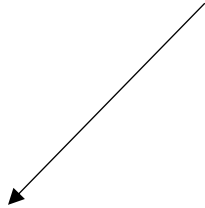
14. Vella MA, Warshauer A, Tortorello G, Long term functional, psychological, emotional, and social outcomes in survivors of firearm injuries. *JAMA Surg.* 2020;151(1):51-59.
15. Navasaria PH, Nicol AJ, Edu S, et al. Selective non-operative management in 1106 patients with abdominal gunshot wounds. *Ann Surg.* 2015;261(4):760-64.

Figure 1: Simplified Consort Diagram

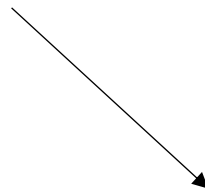
Torso Gunshot Wound (HR \leq 120, SB P \geq 100 mmHg; no diffuse peritonitis)



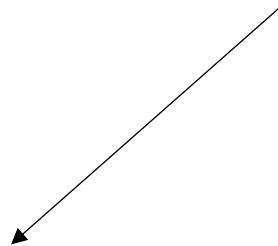
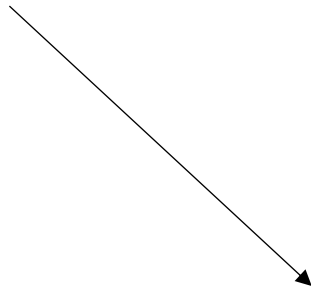
Right Upper Quadrant Wound(s) (see definitions in text)



Immediate Laparotomy



Initial non-operative management (+/- angiography)



Final Study Population:
Isolated liver/right kidney/right adrenal (or no intra-abdominal injuries) identified on CT or OR*

Group Comparisons:

- **Immediate operative vs. successful non-operative**
- Immediate operative vs. delayed operative (failed non-operative)
- Successful non-operative vs. failed non-operative

*Includes patients also identified to have right sided lung/chest wall/diaphragm injuries (thoracoabdominal trajectory)

Form "EAST Multicenter Study Proposal"

Details #120 (submitted 10/15/2020)

Study Title Contemporary Management of Right Upper Quadrant Gunshot Wounds

**Primary investigator /
Senior researcher** Michael A. Vella

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Co-primary investigator Ryan P. Dumas

**Are you a current
member of EAST?** Yes

**If you selected "No"
above please identify a
Sponsor that is an active
EAST member:**

**My Multicenter Study
proposal is...** Prospective

As a result of the understanding of both the short and long term sequela of non-therapeutic laparotomy, the management of penetrating abdominal wounds has evolved significantly from a time of mandatory laparotomy to the contemporary practice of selective non-operative management.[1-4]

Non-operative management of select penetrating abdominal injuries in hemodynamically normal patients without peritonitis is feasible and is currently endorsed by guidelines from both the Eastern Association for the Surgery of Trauma (EAST) and Western Trauma Association (WTA).[5-11] These guidelines recommend that, in the absence of hemodynamic instability and peritonitis, patients with right upper quadrant (RUQ) penetrating injuries (including right thoracoabdominal injuries) be considered for non-operative management. While most studies underlying these recommendations have primarily focused on the feasibility and failure rates of selective non-operative management of these injuries [12], few have evaluated the need for additional abdominal and thoracic interventions between those managed non-operatively compared to those managed initially with operative intervention. A recent retrospective study of primarily blunt grade III and above liver injuries found that operative management was associated with an increased need for unplanned procedures on bivariate analysis, but this association disappeared on logistic regression.[13] Interestingly, firearm injury was independently associated with an increased need for unplanned interventions. There has also been increasing interest in the evaluation of long term outcomes in patients who sustain penetrating injuries [14], and, to our knowledge, no previous studies have specifically examined the long term outcomes in patients with penetrating RUQ wounds.

**Use this area to briefly
(1-2 paragraphs only)
outline the burden of the
problem to be examined**

We hypothesize that selective non-operative management of isolated RUQ gunshot injuries without hemodynamic compromise or peritonitis is feasible and is associated with improved short and long-term outcomes when compared with operative intervention.

We feel that our study is important in that 1) contemporary management and outcomes of RUQ gunshot wounds have not recently been described in a multi-institutional prospective study in the context of management strategies that (in our experience) vary across surgeons and institutions, and 2) to our knowledge, the long term outcomes of patients with gunshot wounds to the RUQ region managed operatively and non-operatively have not been described.

Thus far, we have verbal commitment for study participation from four busy trauma centers (University of Pennsylvania, University of Rochester, University of Texas Southwestern (Parkland), University of Pittsburgh Medical Center), and anticipate that more centers will be interested in participating.

Primary aim

The primary aim of this study is to compare the short and long-term outcomes in patients with RUQ gunshot wounds managed operatively to those initially managed non-operatively

- 1) To describe the current practice patterns for the management of RUQ gunshot wounds in hemodynamically normal patients without peritonitis
- 2) To describe the current failure rate of selective non-operative management of RUQ gunshot wounds
- 3) To identify factors associated with the need for unplanned interventions in this population

Secondary aims

- Isolated RUQ wound(s) as defined below:

- Isolated RUQ (lateral to xiphoid, superior to umbilicus, anterior to anterior axillary line).

- Isolated posterior "RUQ" [15] (between tip of scapula and posterior superior iliac spine in the

cranial-caudal direction and gluteal cleft and posterior axillary line in the medial to lateral direction).

Inclusion Criteria

- Age = 18

• Hemodynamically normal (heart rate, HR, = 120 beats/min and systolic blood pressure, SBP, = 90

mmHg)

- No diffuse peritonitis on abdominal exam

- Age 120 beats/min and/or SBP <90 mmHg)

- Diffuse peritonitis on abdominal exam

- Any gunshot wound not isolated to anterior or posterior RUQ as noted above. Note that right flank

Exclusion Criteria

wounds are excluded by above definitions

- Need for emergency department thoracotomy

- Death within 24 hours of admission

Therapeutic Interventions

As this is a prospective observational study, patients will be managed according to surgeon discretion, and no therapeutic interventions will be recommended as part of the study protocol.

Need for any unplanned intervention, defined as any of the following procedures > 48 hours post admission (similar criteria used in recent study [13]): Endoscopic retrograde cholangiopancreatography (ERCP), interventional radiology intra-abdominal drain placement, angiography +/- embolization, laparotomy/laparoscopy, ureteral stent placement, percutaneous nephrostomy tube placement, thoracotomy, video assisted thoracoscopic surgery (VATS), open or percutaneous chest tube placement. A planned return to the operating room for a patient with an open abdomen will not be considered an unplanned operation unless the laparotomy occurs after the abdomen is closed.

Primary Outcome

(See data collection tool for additional information)

Secondary Outcomes:

-Failure of non-operative management (defined as need for laparotomy during index admission after initial trial of non-operative management)

-Total number of unplanned interventions

-Hospital length of stay (LOS)

-Intensive care unit (ICU) LOS

-30 day hospital re-admission

-In-hospital mortality

Secondary Outcomes

-Intrathoracic complications (biliary-pleural fistula, retained hemothorax, empyema, persistent air leak (>5 days))

-Intra-abdominal complications (bile leak, liver necrosis, intra-abdominal abscess, delayed hemorrhage, pseudoaneurysm development, missed bowel injury)

-Total number of blood products transfused during hospitalization

-Venous thromboembolism (DVT/PE)

-Discharge disposition (home, long-term acute care, acute rehab facility, skilled nursing facility)

-Total number chest/abdominal/pelvis CT scans/MRI studies during index admission

-Need for chest tube and/or intra-abdominal drain at discharge

-6-month outcomes (PROMIS-29 Profile v2.1 metric, attached, as well as 6-month re-admissions, ED visits, and work status)

(see data collection tool for details)

Overview of variables to be collection:

-Demographic variables

-Initial emergency department (ED) physiology

-Initial ED laboratory values

**List specific variables to
be collected & analyzed**

-Initial and 24 hour blood product usage

-Past medical history

-Injury characteristics

-Initial ED management variables

-Post-ED management variables (including operative and post-operative management if applicable)

-Short and long-term outcome variables

Standardized data will be collected for each patient (see data collection tool). Descriptive statistics will be used to describe current management strategies. Outcomes will be compared between those who underwent immediate operative intervention vs. successful selective non-operative management, between those who underwent immediate operative management vs. those who underwent operative management (laparotomy) after failing selective non-operative management, and between those who underwent successful non-operative management vs. failed non-operative management. Importantly, we will be comparing outcomes in patients with isolated liver/right kidney/right adrenal injuries (or no injuries) identified on either initial CT scan or operative intervention when applicable (see Figure 1). Right sided chest wall, right lung, and right diaphragm injuries are included as well. By comparing only patients with these injury patterns we are comparing operative vs. non-operative outcomes in patients with injuries that potentially could be managed non-operatively to mitigate confounding by indication. We will also compare operative vs. non-operative management in the a-prior assigned subgroup of right sided thoracoabdominal (TA) injuries (injuries that involve right chest wall/lung/diaphragm in addition to right upper quadrant solid organs).

Student's t-test will be used for parametric data and Mann Whitney-U test for non-parametric data. X2/Fishers exact tests will be used to compare differences between categorical variables when appropriate. Univariate and multivariable logistic regression will be used to determine factors associated with need for unplanned procedures (all variables with a p value <0.2 on univariate analysis will be entered into a multivariable logistic regression analysis). Statistical significance will be set at 0.05. We do have availability of statisticians at the primary site.

Outline the data collection plan and statistical analysis plan succinctly

A recent study evaluating operative vs. selective non-operative management of blunt and penetrating grade III and above liver injuries found that 26% of patients with penetrating injuries required an unplanned procedure, compared to 15 % overall. Overall, 24% of those managed operatively required delayed intervention compared with 8% of those managed non-operatively. Although our population is obviously different, using these findings, a sample of 74 total patients would be required to show this statistical difference with 80% power at an alpha of 0.05.

We recognize that including 6 month long-term outcomes data using the PROMIS–29 Profile v2.1 metric will add additional work to the project in that these patients will need to be contacted by telephone after hospital discharge. However, we feel that this is important information to obtain when evaluating operative vs. non-operative management. In addition, we expect that any individual center will have 10-20 patients over the study period, and we hope that this will not add a significant amount of work for each center. A standardized script will be provided in order to carry out 6-month telephone interviews. Please see reference 14 for an example of how PROMIS instruments have been used in the penetrating trauma population.

With respect to timeline, we anticipate 1.5 years of data collection, including 1 year of

prospectively identifying patients who meet inclusion criteria followed by an additional 6 months to allow evaluation of 6 month outcomes without accruing new patients.

All data plan will be entered into a password-protected REDCap database (Vanderbilt University, Nashville, TN) after appropriate data share agreements are completed.

Written informed consent will be required for subjects to complete the baseline and 6-month PROMIS metric and long-term outcomes questions. A standardized consent form will be provided that can be altered based on institutional requirements.

Outline consent procedures here, if applicable

Succinctly outline a risk/benefit analysis

The main risk associated with this type of prospective observational study is a data/confidentiality breach which will be mitigated through appropriate data handling as outlined in each individual IRB application. This risk is thought to be minimal. Benefits include a better understanding of current practice patterns for the management of RUQ gunshot injuries as well as those associated with operative vs. non-operative intervention with the ultimate goal of improving the short and long term care of this patient population.

1. Leppaniemi A, Salo J, Haapiainen R. Complications of negative laparotomy for truncal stab wounds. J

Trauma. 1995;38(1):54-8.

2. Li T, Robertson-More C, Maclean AR, et. al. Bowel obstructions and incisional hernias following

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3. Morrison JE, Wisner DH, Bodai BI. Complications after negative laparotomy for trauma: long-term

follow-up in a health maintenance organization. J Trauma. 1996;41(3):509-13.

Include a brief listing of key references

4. Hasaniya N, Demetriades D, Stephens A, et. al. Early morbidity and mortality of non-therapeutic

operations for penetrating trauma. Am Surg. 1994;60(10):744-7.

5. Martin MJ, Brown CVR, Shatz DV, et. al. Evaluation and management of abdominal gunshot wounds:

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