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Research paper

# Improving splenic conservation rate after trauma by applying a protocol for non-operative management and follow-up: A propensity-score analysis

Paola Fugazzola[1,*], Sofia Battisti[2], Matteo Tomasoni[1], Stefano Magnone[3], Michele Pisano[3], Dario Piazzalunga[3], Marcello Bisulli[2], Emiliano Gamberini[4], Vanni Agnoletti[4], Federico Coccolini[5], Emanuela Giampalma[2], Luca Ansaloni[3]

[1]General and Emergency Surgery Unit, Bufalini Hospital, Cesena, Italy
[2]Radiology Department, Bufalini Hospital, Cesena, Italy
[3]General and Emergency Surgery Unit, ASST Papa Giovanni XXIII, Bergamo, Italy
[4]Intensive Care Unit, Bufalini Hospital, Cesena, Italy
[5]Emergency Surgery Unit, State University of Pisa, Cisanello Hospital, Pisa, Italy
[6]General and Emergency Surgery Unit, IRCCS San Matteo Hospital, University of Pavia, Pavia, Italy.
*Email: paola.fugazzola@gmail.com

## ABSTRACT

**Background:** There are shared guidelines about Non-Operative Management (NOM) of splenic injuries, but some unanswered questions remain. The aim of the present study is to establish the usefulness of a standardized protocol for management and follow-up of NOM patients with splenic injuries.

**Methods:** Multicenter retrospective observational study including patients with major blunt trauma (ISS >15) with splenic injuries managed between January 1st 2014 and December 31st 2016 in two Italian I level Trauma Centers: one with a standardized management and follow-up protocol for NOM (Bufalini Hospital, Cesena, BH), and the other without it (ASST Papa Giovanni XXIII Hospital, Bergamo, PG23H). Comparison between patients' outcomes were performed and a propensity score model was calculated.

**Results:** 47 patients managed in BH and 49 patients in PG23H were included. In BH, a higher proportion of patients was treated with NOM (72.3 % vs. 53.1 %, p = 0.051). There was no difference in complication rate and mortality in patients treated with NOM in the two hospitals. A borderline significant trend to a higher NOM failure rate in PG23H was found (BH 0.0 % vs. PG23H 11.3 %, p = 0.076). The total splenic conservation rate was significantly higher in BH (BH 72.3 % vs. PG23H 46.9 %, p = 0.011). After the Propensity Score based matching, 72 patients were included and the total splenic conservation rate was significantly higher in BH (BH: 77.8 % vs. PG23H: 50.9 %, p = 0.014).

**Conclusions:** The application of a protocol for in-hospital management and follow-up for NOM of patients with splenic injury could decrease the NOM failure rate and improve splenic conservation rate.

*Keywords:* spleen trauma, non-operative management, trauma care, non-operative management failure,

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## INTRODUCTION

The non-operative management (NOM) of splenic injuries in hemodynamically stable patients, without associated injuries requiring laparotomy, is nowadays universally considered the gold standard[1,2]. Compared to operative management (OM), NOM is associated with a lower complication and mortality rate, less cost, less need of red blood cells (RBC) transfusions and, above all, it allows the preservation of the immunologic function of the spleen[2–4]. Universally shared guidelines about the topic have been published[1,2] and validated[5], but some unanswered questions on the patients' management and follow-up remain. There are not enough literature available to make recommendations regarding frequency of hemoglobin measurements, intensity and duration of monitoring, time to initiate oral intake, duration and intensity of restricted activity (both in-hospital and after discharge) and timing of initiating deep venous thrombosis (DVT) prophylaxis[2]. Over all, there is not clear information about necessity of radiological follow-up and regarding the timing and type of imaging (Computer Tomography, CT vs. Contrast Enhanced Ultrasound, CEUS); thus patients' management and imaging follow-up is usually based on clinical judgment and has been widely debated[1,6–10]. Although CT is a highly specific and reliable technique, there is no consensus about the use of repeated CT routinely. To limit the risk of ionizing radiation, follow-up CT during NOM should not be indicated, unless the clinical parameters change. CEUS is a valid non-invasive alternative modality, able to monitor patients regardless of the clinical status.

The aim of the present study is to establish the usefulness of a standardized management and follow-up protocol for NOM of splenic injuries in patients with major trauma and its effectiveness in improving outcomes.

## METHODS

The present study is a multicenter retrospective observational study including patients with major trauma (Injury severity score, ISS $>15$) with blunt splenic injuries recorded in the Trauma Registries and managed in two Italian I Level Trauma Centers between January 1$^{st}$, 2014 and December 31$^{st}$, 2016: one with a standardized management and follow-up protocol for NOM of splenic injuries (Bufalini Hospital in Cesena, BH), and the second without a shared protocol, where imaging follow-up and management were based on individual doctor's clinical judgment (ASST Papa Giovanni XXIII Hospital in Bergamo, PG23H). Exclusion criteria were ISS $\leq 15$, age $<16$ years and death for other causes than splenic injuries in the first 24 hours from trauma. The protocols of the BH for minor (defined as splenic injuries which do not need angioembolization, with a hemoperitoneum estimated amount $<500$ ml, without CT contrast pooling) and major splenic injuries (splenic injuries treated with angioembolization, with a hemoperitoneum amount higher than 500 ml or with CT contrast pooling) are shown in Figure 1 and includes both indications for radiological follow-up and indications for management (timing for mobilization, frequency of hemoglobin measurements, frequency and duration of monitoring, time to initiate oral intake, timing of initiating DVT prophylaxis, timing for bladder catheter removal). The CEUS follow-up protocol provides execution of three scans, one on the first day from trauma (between 12-24 hours), follows on the third day (between 48-72 hours) and during pre-discharge on eighth day from the admission. During hospitalization, CT is performed only in three scenarios: in case of ultrasound doubt or detection of complication insurgence during CEUS follow-up; in case of unexpected sudden modification of clinical and/or laboratoristic conditions; or after 24 hours from the admission in case of presence of contrast pooling highlighted during first CT scan, but not confirmed during angiography. Post-discharge CEUS is performed at 15, 30 and 60 days from the trauma. Continuous monitoring of vital signs is indicated for the first 48 hours, then every 8 hours; CBC controls every six hours in the first 24 hours for both injury grades, then every 12 hours on second day and once on the third day for major splenic injuries, while once a day on second and third days for minor injuries. Control of PT-PTT is indicated on the first day for both injury grades. Bladder catheter removal is recommended on the second day for minor and on the third day for major splenic injuries. Mobilization out of bed is allowed on the second day for minor and on fifth day for major splenic injuries. DVT prophylaxis with LMWH is introduced on the second day for minor and on the fifth day for major splenic injuries. A light diet is allowed on the second day for minor and on the third day for major splenic injuries. Empiric antibiotic therapy is not recommended. In case of fever insurgence, blood cultures and targeted antibiotic therapy are suggested (Figure 1).

Patients' characteristics (age, gender, Injury Severity Score, ISS), data about management (NOM vs. OM, angioembolization, AE) and outcome (complications related to splenic trauma, mortality for all causes, specific mortality related to splenic trauma and NOM failure) were retrospectively collected. A

A)

| Minor splenic injury | | | | | | |
|---|---|---|---|---|---|---|
| | Day 1 | Day 2 | Day 3 | Day 5 | Day 7 | Day 8 |
| Vital signs detection | Continuous monitoring (BP, HR, SatO2) | | BP, HR, SatO2 every 8 hours | | | |
| CEUS | Yes | No | Yes | No | No | Yes |
| CBC | Every 6 hours | Yes | | No | | Yes |
| PT-PTT | Yes | No | | | | |
| Bladder catheter | Yes | Bladder catheter removal | No | | | |
| Mobilization | No | Yes | | | | |
| Deep venous thrombosis prophylaxis | DVT compressi on stockings | DVT compression stockings + LMWH | | | | |
| Diet | Fasting | Light diet | Free diet | | | |
| Antibiotic therapy | No. Iffever →perform blood coltures and administer targeted antibiotic therapy | | | | | |

FOLLOW-UP: CEUS after 15-30-60 days from discharge. In case of incomplete healing after 60 days, perform MRI.

B)

| Major splenic injury | | | | | | |
|---|---|---|---|---|---|---|
| | Day 1 | Day 2 | Day 3 | Day 5 | Day 7 | Day 8 |
| Vital signs detection | Continuous monitoring (BP, HR, SatO2) | | BP, HR, SatO2 every 8 hours | | | |
| CEUS | Yes | No | Yes | No | No | Yes |
| CBC | Every 6 hours | Every 12 hours | Yes | No | | Yes |
| PT-PTT | Yes | No | | | | |
| Bladder catheter | Yes | | Bladder catheter removal | No | | |
| Mobilization | No | | | Yes | | |
| Deep venous thrombosis prophylaxis | DVT compression stockings | | | DVT compression stockings + LMWH | | |
| Diet | Fasting | | Light diet | Free diet | | |
| Antibiotic therapy | No. Iffever →perform blood coltures and administer targeted antibiotic therapy | | | | | |

FOLLOW-UP: CEUS after 15-30-60 days from discharge. In case of incomplete healing after 60 days, perform MRI.

**Figure 1. BH management and follow-up protocol for minor splenic injuries [no angioembolization, haemoperitoneum < 500cc, no CT active bleeding] (A) and major splenic injuries [angioembolization or haemoperitoneum > 500cc or CT active bleeding] (B).**
**(BP, Blood Pressure; HR, Heart Rate; SatO2, Oxygen Saturation; CEUS, Contrast Enhanced Ultra Sound; CBC, complete blood count; PT, Prothrombine Time; PTT, Partial Thromboplastin Time; DVT, Deep Venous Thrombosis; LMWH, Low Molecular Weight Heparin)**

radiologist to define the American Association for the Surgery of Trauma (AAST) grade according to 2018 last version of splenic injuries and the presence of CT "contrast pooling" indicating an active bleeding reviewed all CT scans.

We defined OM when patient underwent urgent surgical intervention at arrival in the ED and if during surgery, splenectomy or hemostatic splenic technique (e.g. splenic packing or splenorrhaphy) were performed. Conversely, AE was included in NOM. AE was performed in case of CT active bleeding or in case of high AAST grade, even without a positive CT for presence of contrast pooling, according to interventional radiologist's judgment. NOM failure was defined as the need of performing splenectomy after starting NOM, for any cause.

## Statistical analysis

Comparison between patients' characteristics and outcomes of the two Trauma Centers were performed with students' t-test for continuous variables with normal distribution and with the Mann-

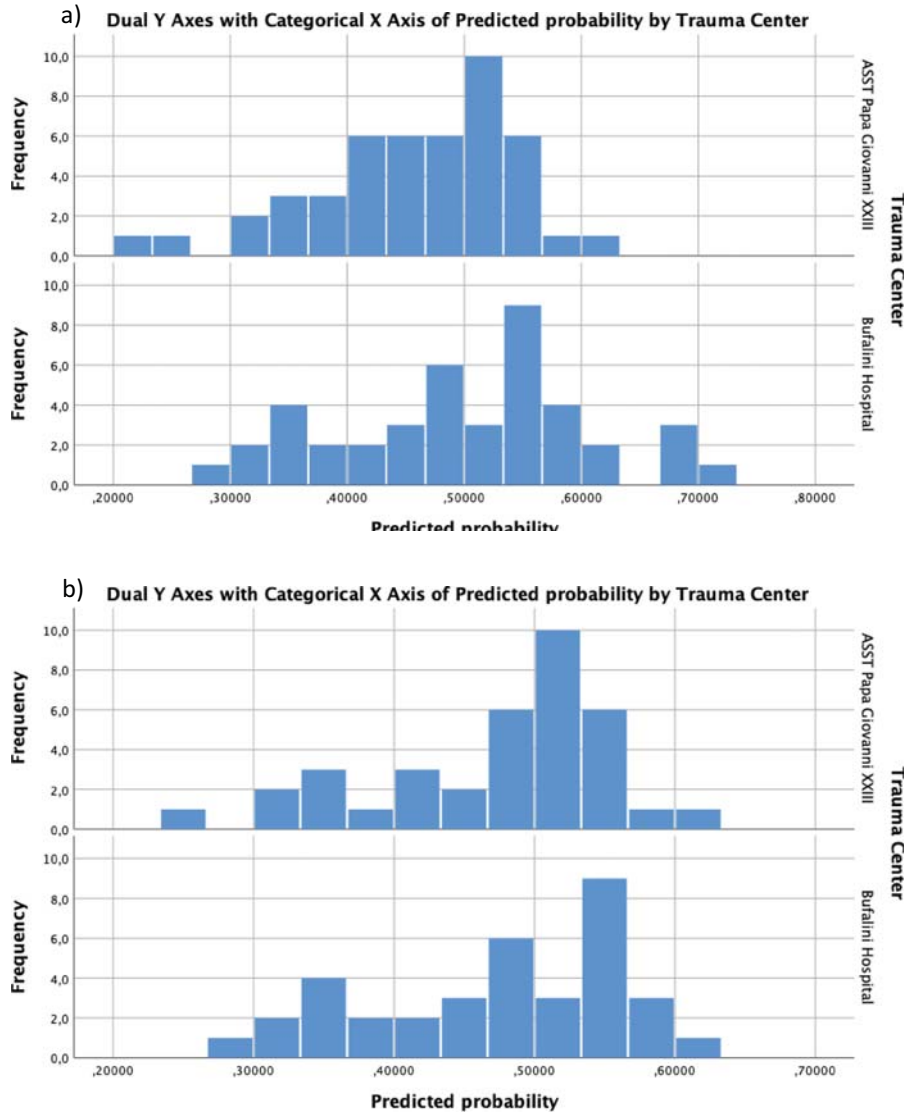


**Figure 2. Histograms of propensity scores between the two Trauma Center before (a) and after (b) Propensity Score based matching.**

Whitney test for non-normal distribution variables. Parametric variables were compared with chi-square or Fisher test, as appropriate.

The comparison relatively to the outcomes was first made on the total of the patients of the two populations included. Then, in order to reduce variability and heterogeneity among included patients, and reduce selection bias, a propensity score (PS) model was calculated considering as covariates the patients' age, ISS, gender and American Association for the Surgery of Trauma (AAST) splenic injury grade. Patients treated in the hospital with a standardized protocol were matched in a proportion of 1:1 with patients treated in the hospital without a standardized protocol using the nearest neighbor based on the PS with a match tolerance of 0.05.

Significant *p*-value was considered lower than 0.05. SPSS 26 (IBM SPSS Statistics for Windows, version 24.0; IBM Corp., Armonk, NY, USA) was used for statistical analysis.

## RESULTS

### Splenic injury group

The study included 96 patients with major trauma (ISS >15) with blunt splenic injuries managed between January 1$^{st}$, 2014 and December 31$^{st}$, 2016: 47 in BH and 49 in PG23H. Characteristics, management (OM vs. NOM) and outcomes of patients of the two hospitals are reported in Table 1.

**Table 1. Characteristics of splenic trauma patients**

| Variables | | Total N=96 | BH N=47 | PG23H N=49 | P value* |
|---|---|---|---|---|---|
| Male gender | N (%) | 70 (72,9) | 33 (70,2) | 37 (75,5) | 0,648 |
| Age | Mean± SD<br>Median (Range) | 49,4± 19,1<br>49 (17-94) | 49,1± 22,0<br>46 (17-94) | 49,8± 15,8<br>49 (21-82) | 0,934 |
| ISS | Median (IQR) | 27 (13,0) | 25 (12,0) | 27 (12,0) | 0,501 |
| Splenic injuries AAST grade >3 | N (%) | 26 (28,9) | 11 (26,2) | 15 (31,3) | 0,647 |
| NOM | N (%) | 60 (62,5) | 34 (72,3) | 26 (53,1) | 0,051 |
| Complications related to splenic trauma | N (%) | 19 (20,9) | 7 (15,6) | 12 (26,1) | 0,217 |
| Deaths for all causes | N (%) | 8 (8,3) | 5 (10,6) | 3 (6,1) | 0,482 |
| Causes of deaths | Description (%) | / | 1 (20) for liver trauma<br>4 (80) for head injury | 1 (33,3) for septic shock<br>1 (33,3) for retroperitoneal hematoma<br>1 (33,3) for myocardial infarction | / |
| Splenic trauma specific deaths | N (%) | 0 (0,0) | 0 (0,0) | 0 (0,0) | / |

BH: Bufalini Hospital Cesena, PG23H: ASST Papa Giovanni XXIII Hospital Bergamo, ISS: Injury Severity Score, AAST: American Association for the Surgery of Trauma. *probability between BH and PG23H, IQR: interquartile range, NOM: non-operative management

The two groups were comparable in terms of gender, age, ISS and rate of patients with AAST splenic injury grade >3. There was no significant difference in complication rate (BH: 15.6 % vs. PG23H: 26.1 %, p = 0.217) and mortality rate for all causes (BH: 10.6 % vs. PG23H: 6.1 %, p = 0.482) between the two I Level Trauma Centers. In BH, a significant higher proportion of patients was treated with NOM than in PG23H: respectively 72.3 % vs. 53.1 %, p = 0.051).

## NOM group

A total of 60 patients were treated with NOM (34 in BH and 26 in PG23H) (Table 2). The two NOM groups were comparable in terms of age, gender, ISS, AAST grade, proportion of patients with CT active bleeding and treated with AE. There was no significant difference in term of complication rate (BH: 15.2 % vs. PG23H: 26.9 %, p = 0.209) and mortality rate for all causes (BH: 5.9 % vs. PG23H: 3.8 %, p = 1.000). In BH, 5 patients had complications: one splenic abscess, one pseudoaneurysm, and three pulmonary complications (left pleural effusion/left basal pneumonia). In PG23H, 7 patients had complications: two abscesses, one 20 cm peri-splenic hematoma, 4 re-bleedings. Complications occurred in patients with AAST injury grade ranging from I to IV. Three patients failed NOM and underwent splenectomy, all of them in PG23H: one for abscess formation, one for 20 cm-hematoma formation, one for re-bleeding. NOM failure occurred in patients with AAST injury grade III and IV. A borderline significant trend to a higher NOM failure rate in PG23H was found (BH: 0.0 % vs. PG23H: 11.3 %, p = 0.076).

The total splenic conservation rate was significantly higher in BH than PG23H: respectively 34 patients (72.3 %) in BH and 23 patients (46.9 %) in PG23H (p = 0.011).

## OM group

Definitely, a total of 36 patients were treated with OM at their arrival (13 in BH and 23 in PG23H) (Table 3). The two OM groups were comparable in terms of age, gender, ISS, AAST grade. Patients treated with OM in BH had a higher rate of CT contrast pooling (38.4 % vs. 4.3 %, p = 0.006). There was

**Table 2. Characteristics of splenic trauma patients treated with Non-Operative Management**

| Variables | | Total NOM patients (n=60) | BH NOM patients (n=34) | ASST PAPA GIOVANNI XXIII NOM patients (n=26) | P value |
|---|---|---|---|---|---|
| Age | Mean± SD<br>Median<br>(Min-Max) | 50,5± 19,0<br>50 (17-94) | 48,5± 21,3<br>46 (17-94) | 52,7± 15,3<br>52 (23-75) | 0,381 |
| Male gender | N (%) | 43 (71,7) | 23 (67,6) | 20 (76,9) | 0,566 |
| ISS | Median<br>(IQR) | 24 (11,0) | 24 (11,3) | 24 (13,5) | 0,929 |
| CT active bleeding | N (%) | 21 (36,8) | 14 (43,8) | 7 (28,0) | 0,275 |
| AAST grade | AAST >3 | 14 (23,3) | 8 (23,5) | 6 (23,1) | 0,967 |
| AE | Total | 25 (41,7) | 16 (47,1) | 9 (34,6) | 0,333 |
| Complication related to splenic trauma | N (%) | 8 (13,6) | 5 (15,2) | 7 (26,9) | 0,209 |
| Complications | Description | 3 abscesses<br>1 PSA<br>1 large hematoma<br>4 re-bleeding<br>3 pulmonary complication | 1 abscess<br>1 PSA<br>3 pulmonary complications | 2 abscesses<br>1 large hematoma<br>4 re-bleeding | / |
| Mortality for all causes | N (%) | 3 (5,0) | 2 (5,9) | 1 (3,8) | 1,000 |
| Specific mortality | N (%) | 0 (0,0) | 0 (0,0) | 0 (0,0) | / |
| NOM Failure | N (%) | 3 (5,0) | 0 (0,0) | 3 (11,3)<br>1 abscess<br>1 large hematoma<br>1 re-bleeding | 0,076 |

BH: Bufalini Hospital Cesena, PG23H: ASST Papa Giovanni XXIII Hospital Bergamo, ISS: Injury Severity Score, AAST: American Association for the Surgery of Trauma. *probability between BH and PG23H, IQR: interquartile range, NOM: non-operative management

no significant difference in complication rate (BH: 15.4 % vs. PG23H: 30.4 %, p = 0.139) and mortality rate for all causes (BH: 23.1 % vs. PG23H: 8.7 %, p = 0.328). In BH, 2 patients had complications related to splenectomy: one abscess and one wound infection, both treated conservatively with antibiotic therapy. In PG23H, 7 patients had complications related to splenectomy. One patient had iatrogenic pancreatic fistula and another patient pancreatitis, which were treated conservatively. One patient had an iatrogenic gastric injury and pancreatitis, and he underwent reintervention. Two patients showed persistent hemorrhagic shock signs even after splenectomy: one of them underwent angiography and angioembolization for persistent active bleeding, and the other underwent reintervention. One patient had sepsis of unknown origin and he was treated with antibiotic therapy. One patient had mechanical intestinal occlusion due to post-operative adhesions and he underwent reintervention. Complications occurred in patients with AAST injury grade ranged from II to V.

## Propensity score analysis

After the PS-based matching, among the 96 initial patients' population, 72 patients were included for the final analysis, 36 treated at BH and 36 treated at PG23H. Table 4 shows detailed population's characteristics before and after PS-based matching and Figure 4 the histogram of PS between the two I Level Trauma Centers before and after PS-based matching. In this PS matched population, the NOM failure rate was lower in the BH, even if without statistical significance (0/28, 0 % vs. 1/18, 5.3 %, p = 0.404) and the total splenic conservation rate was significantly higher in BH (BH: 28/36, 77.8 % vs. PG23H: 18/36, 50.9 %, p = 0.014). After matching patients for age, gender, ISS and AAST splenic injury grade, PG23H, the I Level Trauma Center without a standardized protocol for NOM of splenic injuries, showed an OR for splenectomy (at arrival of patient or for failure of NOM) of 2.250 (95 % CI: 1.125-4.499), compared with BH, the I Level Trauma Center with a standardized protocol.

**Table 3. Characteristics of splenic trauma patients treated with Operative Management**

| Variables | | Total OM patients (n=36) | BH OM patients (n=13) | ASST PAPA GIOVANNI XXIII OM patients (n=23) | P value |
|---|---|---|---|---|---|
| Age | Mean ± SD<br>Median<br>(Min-Max) | 47,57 ± 19,3<br>45,4 (19-86) | 50,7 ± 24,5<br>46 (19-86) | 45,6 ± 15,7<br>44,8 (21-81) | 0,527 |
| Male gender | N (%) | 27 (75,0) | 10 (76,9) | 17 (73,9) | 0,841 |
| ISS | Median (IQR) | 28,5(11) | 30 (10) | 27 (17) | 0,676 |
| CT active bleeding | N (%) | 6 (24,0) | 5 (38,4) | 1 (4,3) | 0,006 |
| AAST grade | AAST >3 | 12 (40,0) | 3 (23,1) | 9 (39,1) | 0,866 |
| Complication related to splenic trauma | N (%) | 11 (34,4) | 2 (15,4) | 7 (30,4) | 0,139 |
| Complications | Description | 3 abscesses<br>1 PSA<br>1 large hematoma<br>4 re-bleeding<br>3 pulmonary complication | 1 abscess<br>1 wound infection | 1 pancreatic fistula<br>1 iatrogenic gastric injury and pancreatitis<br>2 shock persistence<br>1 sepsis<br>1 pancreatitis<br>1 mechanical occlusion for adhesions | / |
| Mortality for all causes | N (%) | 5 (13,9) | 3 (23,1) | 2 (8,7) | 0,328 |
| Specific mortality | N (%) | 0 (0,0) | 0 (0,0) | 0 (0,0) | / |

BH: Bufalini Hospital Cesena, PG23H: ASST Papa Giovanni XXIII Hospital Bergamo, ISS: Injury Severity Score, AAST: American Association for the Surgery of Trauma. *probability between BH and PG23H, IQR: interquartile range, OM: operative management

**Table 4. Population's characteristics and the relative effect sizes before and after Propensity Score based matching**

| Variables | Before matching | | | | After matching | | | |
|---|---|---|---|---|---|---|---|---|
| | BH (n=47) | ASST Papa Giovanni XXIII (n=49) | P value* | Standardized difference (effect size) | BH (n = 36) | ASST Papa Giovanni XXIII (n=36) | P value* | Standardized difference (effect size) |
| Age (mean) | 49,09 | 49,41 | 0,934 | 0,02 | 49,36 | 47,48 | 0,680 | 0,098 |
| Gender male (n (%)) | 33 (70,2) | 37 (75,5) | 0,564 | 0,13 | 28 (51,9) | 26 (48,1) | 0,592 | -0,14 |
| ISS (mean) | 26,87 | 28,15 | 0,501 | -0,14 | 27,31 | 26,92 | 0,851 | 0,044 |
| AAST (mean) | 2,62 | 2,96 | 0,186 | -0,28 | 2,78 | 2,94 | 0,568 | -0,13 |

BH: Bufalini Hospital Cesena, PG23H: ASST Papa Giovanni XXIII Hospital Bergamo, ISS: Injury Severity Score, AAST: American Association for the Surgery of Trauma. *probability between BH and PG23H

## DISCUSSION

Although the concept of NOM in splenic injuries is widely accepted, it continues to be controversial due to the lack of well-designed randomized studies on different aspects of specificities of conservative treatment, like the need of patients' in-hospital management and type and timing of follow-up.

Indeed, NOM of splenic injuries is burdened by a significant percentage of complications and failures. Actually, NOM failure rate ranges from 1 to 15 %[11–24]. It is not clear whether taking specific measures in the intra-hospital management of these patients could reduce the rate of complications and failure. In addition, it is not even established whether following a standardized instrumental follow-up could diagnose the complications earlier, so they could be treated before causing NOM failure.

In a series of 30 patients treated with NOM for splenic injuries with success, Lyass et al., compared two group of patients: 8 patients had only initial ultrasound and CT scan, 22 patients underwent repeat follow-up ultrasound or CT scan. In the second group, follow-up studies showed deterioration only in one patient, without changing his management. In this work, there was no standardized protocol and radiological imaging performed according to the discretion of the attending surgeon[6].

In another study by Liechti et al., on 102 NOM patients, 80 patients received follow-up imaging. Among these, 57 patients received routine imaging examinations without prior clinical deterioration and the 96.4 % of these imaging results revealed no new significant findings. The authors concluded that indication for radiological follow-up should be based only on clinical findings[7].

On the other hand, in the study by Leeper et al.,[25], of 475 patients selected for NOM, approximately 5 % were found to have high-risk lesions on their initial CT scan, while an additional 6 % went on to have high-risk lesions (pseudoaneurysms and/or CT active bleeding) on follow-up CT imaging.

Davis et al., showed that follow-up CT scans at 24 hours to 48 hours could be combined with AE to produce an impressive reduction in the rate of NOM failure to as low as 3 %[26].

Savage et al.,[27] demonstrated that the 10.3 % of patients with splenic trauma had worsening of their injury on repeated CT after 24-72 hours from trauma. The 26 % of patients with mild spleen injuries and the 59 % of patients with severe spleen injuries that worsened as in-patients underwent angioembolization secondary to pseudoaneurysm finding at follow-up CT-scan.

Despite this evidence, the routine use of follow-up imaging has not been universally embraced. Actually, a recent survey performed in 2019 showed that 62 % of institutions did not have a routine protocol for follow-up imaging for splenic trauma[10].

Focusing on radiological follow-up modality, CEUS is widely accepted. In a study on 139 trauma patients with splenic injuries, CEUS and contrast-enhanced CT scan diagnostic comparability was 98.6 % and, compared to angiography, CEUS showed a sensitivity of 100 % and a positive predictive value of 91.7 %[9]. The authors concluded that CEUS could be used during spleen injury follow-up instead of contrast-enhanced CT.

Regarding other aspects of patients' management, the fact that LMWH-based prophylactic anticoagulation should be started as soon as possible from trauma and may be safe in selected patients with blunt splenic injury undergone to NOM is now shared[1], even if the exact timing has not yet been established.

While some authors tried to establish the timing to return to normal activities[28–29], the optimal timing for in-hospital mobilization has not yet been found. Teichman et al.,[30] applied a protocol for early mobilization of NOM patients: patients in the low-grade injury group were observed with bed rest overnight until two successive hemoglobins 12-h apart were within 10 % of each other; patients with high-grade injuries were admitted to the ICU and kept on bed rest until three successive hemoglobins 8-h apart after the first were within 10 % of each other. Authors showed significantly decreased length of stay and cost in the group of patients earlier mobilized, without difference in NOM failure, angiography/embolization, or mortality.

Some authors stressed the importance of having a multidisciplinary protocol that regulates patient management and follow-up[31,32], but a shared algorithm does not exist and no comparative studies between patients treated with and without a standardized protocol have been performed yet.

In the present study, the absence of a protocol for the management of splenic trauma in one of the two I Level Trauma Centers did not affect mortality and complication rate related to splenic trauma, probably because both centers are regional HUBs for trauma with wide spread individual expertise in trauma management. At the BH, a slight non-significant trend for a greater mortality for other causes than splenic trauma was found, because 80 % of deceased patients died for the concurrent cranial trauma. However, major trauma patients managed in the institution with a standardized protocol for NOM for splenic injuries had no failures, showing a borderline significant trend to a lower NOM failure rate compared to the institution without standardized protocol, despite the fact that BH had even a higher rate of patients treated with NOM than PG23H. Therefore, the application of the protocol seems to result in a significantly higher splenic salvage rate.

The limits of the present study are the retrospective nature of the study, the small sample size and the fact that patients did not have isolated splenic injury and so the associated lesions could have partly influenced results. Unfortunately, this is the limit of all studies on polytrauma patients. However, since the two groups were comparable in term of ISS, this bias might not be considered.

The follow-up and management protocol of NOM splenic injury of trauma patients in BH includes both indications for in-hospital management (timing for mobilization, frequency of hemoglobin measurements, intensity and duration of monitoring, time to initiate oral intake, timing of initiating DVT prophylaxis, timing for bladder catheter removal) and for radiological follow-up (CEUS). In our opinion, the lower NOM failure rate in BH could be the result of the standardized radiological follow-up more than the effect of the indications for in-hospital management. In fact, the radiological follow-up protocol could allow diagnosing complications, re-bleeding earlier, and treating them before they cause NOM failure. Furthermore, the awareness that the patient with splenic trauma treated with NOM is subjected to a strict radiological monitoring protocol can increase operators' confidence in the safety of conservative treatment. Finally, these results confirm that the culture of organization according to protocols, even in trauma management, is of support to the clinicians in the individual choice on the best therapeutic strategy[33]. In this view may be suggested that the presence of a standardized protocol could be even more useful in lower level trauma centers, where the individual expertise in the trauma management could be lesser and operator dependence could affect the quality of care.

## CONCLUSION

The application of a standardized protocol for in-hospital management and follow-up for NOM of patients after splenic injury could raise clinicians' self-reliance in NOM, thus increasing confidence in making the decision to treat a patient with splenic trauma with NOM, as well as decreasing, with a borderline significant trend, the NOM failure rate, finally improving splenic conservation rate.

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### Declarations

### Conflict of Interest

All authors declare no conflict of interests

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### Statements on human and animal rights

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000.

### Informed consent

Informed consent was obtained from all patients before inclusion in the study.

### Ethics approval

ASST Papa Giovanni XXIII: data were retrospectively extracted from the official ASST Papa Giovanni XXIII Trauma Register; Bufalini Hospital: Ethical approval protocol number 7630/2019 I.5/136

### Author contribution

P.F., S.B., M.T., L.A., contributed to the design and/or implementation of the research, P.F., S.B., M.T., M.B., S.M., D.P. contributed to the collection of data, P.F., S.B., M.T., S.M., M.P., D.P., M.B., E.G., V.A., F.C., E.G., L.A. contributed to the analysis of the results, P.F., S.B., S.M., M.P., L.A. contributed to the writing of the manuscript. All authors revised and approved the final manuscript.

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