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State of the art

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AIM: *To evaluate the advantages and potential risks of "Non Operative Management" (NOM) in order to redifine the technique into the true gold standard and to extend its application to the emergency care of blunt splenic trauma.*
MATERIALS AND METHODS: *Blunt trauma cases treated between 2004 and 2019 have been retrospectively evaluated. Every patient has been distributed at the hospital admission in 3 different groups: stable, unstable and transient responder according to ATLS. NOM exclusion criteria were only introduced in 2013: we therefore assessed datas before and after this year.*
RESULTS: *Over a period of 15 years, approximately 6 patients per year were admitted to our hospital with a spleen injury. After the introduction of the NOM protocol in 2013, the proportion of splenectomies progressively decreased. This rate also increased for higher injury grades. The overall number of patients who underwent NOM was 40 (43%), but while between 2004 and 2012 only 25% of patients were managed with NOM, between 2013 and 2019 70.3% of patients were treated with NOM.*
CONCLUSIONS: *Nowadays any blunt splenic trauma could, theoretically, undergo NOM, regardless of the grade of the injury; the only strict criteria for OM should be haemodynamic instability; this assumption depends, of course, on hospital's human and technological resources.*

KEY WORDS: Non operative management, Splenic trauma, Splenectomy

Introduction

In the past few decades the management of blunt abdominal trauma has shifted towards a more conservative approach, the so called "non operative management" (NOM). This could be explained by recent advances in diagnostic imaging, by the implementation of interventional radiology techniques and by the increased knowledge of anatomy and physiology of the spleen. Non operative management involves prolonged watchful waiting and it is based on the spleen's natural wound healing ability [1]; implementation of this method could lead to a decreased number of unnecessary splenectomies. NOM relies on patient's monitoring with frequent, regular clinical assessment, on appropriate laboratory investigations, and on reevaluating management options, if indicated. This approach may decrease not only the number of urgent splenectomies performed, but also post-splenectomy infections. At first, NOM was applied to pediatric patients, with shorter hospital stay, less need for blood transfusions and antibiotic therapy, as well as reduced rate of infections [2]. Nowadays, blunt abdominal trauma should be manged by a multidisciplinary team that includes an anaesthetist, a general surgeon and also an orthopaedic. NOM is considered to be the gold standard for the treatment of

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patients with blunt splenic trauma who are haemodynamically stable after initial resuscitation, without peritonitis and associated injuries requiring laparotomy [3]. The aim of our paper is to assess splenic trauma treatment, evaluating the advantages and potential risks of NOM, in order to determine the real rate of feasibility and safety of NOM in severe trauma patients.

Material and methods

We performed a retrospective study that included patients with blunt splenic trauma treated between January 2004 and December 2019 at our Institution. During this time, our management of splenic trauma has considerably changed, in favour of NOM. From 2013 onwards, NOM became the gold standard both in children and in adults. In addition, a management protocol to standardize splenic trauma approach, an in-hospital procedure flow-chart and indications for patient discharge and follow up were introduced. In the ninth edition of Advanced Trauma Life Support (ATLS), patients are defined as "unstable" when their blood pressure is < 90 mmHg and/or their heart rate > 120 bpm, with evidence of skin vasoconstriction and altered level of consciousness. According to ATLS, patients have been classified in 3 different categories:
– Stable;
– Transient responder (showing an initial response to adequate fluid resuscitation and then signs of ongoing loss and perfusion deficits);
– Unstable.

The parameters considered were as follows: blood gas analysis, systolic and diastolic artery pressure, heart rate and breathing rate. Ideal systolic blood pressure values were set at 90 mmHg for isolate blunt abdominal trauma and 110 mmHg in the event of associated cranial trauma. An Injury Severity Score (ISS) was calculated for each patient, as well as the presence of associated abdominal, pelvic or cerebral lesions. For all patients, information on patient demographics, type of management, radiology, surgical details and post operative outcomes were retrospectively gathered and analysed. The main outcomes evaluated included mortality rate, length of hospital stay, rate of treatment success and complications. A standardized emergency care protocol was used to manage trauma cases at our Institution. Focused Assessment with Sonography for Trauma (FAST) was performed in all patients to diagnose haemoperitoneum. Selective abdominal/thoracic/cranial or full-body dual or triple phase CT scan was performed in all haemodynamically stable patients.
In patients with severe iodine allergy or poor renal function, a non-contrast enhanced CT scan was chosen as the first diagnostic step. According to the ATLS guideline, in every patient with hypotension (< 90mmHg) and tachycardia (> 100 p/min), 2000 ml of intravenous fluids were rapidly administrated. Patients that showed haemodynamic improvement in the emergency department, even in the event of mild persistent tachycardia (< 110 p/min), were considered as responders. Patients admitted with hypotension and tachycardia and whose condition was deteriorating despite resuscitation, and presented no other obvious bleeding sites, underwent emergency laparotomy. Exclusion criteria for NOM included:
– need for more than 3 Units of blood transfusion in order to obtain haemodynamic stability;
– presence of peritonitis at the time of admission;
– presence of other non-abdominal major lesions requiring immediate surgical intervention;
– impossibility of adequate follow up.

Patients requiring surgery within 12 hours from their arrival in emergency department were included in the operative management (OM) group. Both early (within 72 hours after admission) or late (after 7 days) failure of NOM was defined as:
– onset of hypotension, tachycardia and oligo/anuria according to ATLS parameters;
– decrease of haemoglobin with progressive increase of haemoperitoneum;
– need for at least 4 U.I. of blood within the first 24 hours in order to mantain haemodynamic stability.

Spleen re-bleeding within 30 days could also occur after discharge from hospital and it is often associated with pseudo aneurysm or vascular anomalies.
Every splenic trauma was classified according to a grading system developed by the American Association of the Surgery of Trauma (AAST) and it is based on the anatomic disruption of the spleen (Table I). Grade I and II injures, were admitted to a less intensively monitored setting. All grade III injures or above were admitted in the intensive care unit.
Watchful waiting time is still under discussion and the clinical condition of the patient should be considered in the decision making process. Our standard practice is to keep the patient under observation for at least three days by monitoring the haematocrit and vital signs, that must be measured every 6 hours on the first day, every 12 hours until the third day and every 24 hours until patient discharge [4].
Mortality was identified as any death occurring during the entire hospital stay or within the first 30 days from trauma and linked to the splenic rupture.
Statistical analysis
Data were expressed as mean ± standard deviation for continuous variables and as frequency and percentage for categorical variables. Differences between the two groups were analyzed with student t-test for continuous variables and χ^2 test for categorical variables. A p-value <0.05 was considered as statistically significant.

Results

The study included 93 adult patients treated for blunt splenic trauma between January 2004 and December 2019 at our Institution, with an average of 5.8 patients/year and with a median age of 53.8 years (Table II); the male/female ratio was 2.58:1 with a male prevalence of 72%. Between 2004 and 2012, we treated 56 cases: 42 patients were managed with OM (75%), while 14 patients with NOM (25%). The average hospital stay was 8.6 days and the mortality rate was 8.9% resulting from the death of 5 patients. All deceased patients were in the Operative Management group and the cause of death was related to the severity of the general trauma and not to the splenic trauma per se. Between 2013 and 2019 a total of 37 patients with blunt splenic trauma were admitted in our emergency department: 26 of them were treated with NOM (70.3%) and 11 with OM (29.7%) The average hospital stay was 7.4 days. The mortality rate was 8.1% and all deceased patients had undergone splenectomy: two patients died for cardiogenic shock and one for brain injuries. The overall morbidity rate was 31.2% (29 patients): 18 cases between 2004 and 2012 and 11 cases between 2013 and 2019. The more frequent complications were pulmonary disventilation and infections . Among the OM group, patients underwent surgery less than 62 minutes (range 35-62 minutes) after arriving in the emergency department. The laparoscopic approach has never been used. We reported no clinical pancreatic fistula, but one case of pseudocyst formation was recorded. Over a period of 15 years, approximately 6 patients per year were admitted to our hospital with a spleen injury. After the introduction of the NOM protocol in 2013, the proportion of patients undergoing open surgery decreased over time. This rate also reduced for higher injury grades. The overall number of patients managed with NOM was 40 (43%). However, after the introduction of the protocol for splenic trauma treatment, according to Literature, this rate could be increased to 70%.

Our results could be improved by using splenic artery embolization. Unfortunately, a 24 hours/day intervention radiology team is unavailable in our emergency department, thus splenic artery embolization can not be performed at our Institution. This limitation could explain our high rate of OM, especially in cases with active bleeding on CT scan. No cases of failure of NOM were reported at our hospital, as patients were carefully selected. Particular attention was paid to "transient responder" patients, and when in doubt, OM was chosen in order to avoid onset of the triad including hypothermia, acidosis and coagulopathy. Among these transient responder patients, injury grade 3 with active bleeding and the need for 3 or more units of red blood cell transfusions were identified as risk factors requiring a switch to operative management. The only case of delayed splenic rupture was caused by an earlier laparoscopic nephrectomy performed 10 days before and occurred after patient discharge.

Discussion

Trauma is the leading cause of death among individuals up to the age of 40. The spleen is the most frequently injured organ following abdominal blunt trauma, and it accounts for around 33% of intra-abdominal injuries. In European countries, the commonest causes of trauma were mostly road traffic accidents or sport and domestic accidents [5]. During most of the twentieth century, the main focus was on the control of bleeding and splenectomy was considered the treatment of choice, since the immune function of spleen was not fully undestood. In the early 70s, Singer described the increased incidence and mortality rates due to overwhelming post-splenectomy infections [6]. In the 80s, after initial experience with paediatric patients, alternative options were explored by surgeons to try to preserve the splenic parenchyma in trauma victims. Recognition of the immune function of the spleen, improved imaging techniques and advances in interventional radiology led to the development of non operative management techniques [7]. Over the years, the approach for diagnosis and management of blunt splenic injury has shifted considerably from operative management to NOM. Most of the current guidelines support NOM or minimally invasive approaches in haemodynamically stable patients [8]. Careful selection of patients is associated with a higher success rate and a lower morbidity and mortality rate. In addition, failure of NOM has been shown to be associated with increased resource use and higher mortality [9]. Clinical presentation can sometimes be misleading: some cases of high grade blunt splenic trauma could be successfully treated conservatively, while some patients with lower grade injury may end up with delayed splenic rupture. In fact, reported failure rates of NOM have ranged as high as 15%. In addition, the need for red blood cell transfusion in the emergency department superior to 3 Units seems to be a factor associated with failure of NOM [10]. Scientific Literature has recently shown that conservative treatment represents a safe and effective treatment option and it is not necessarily contraindicated in major splenic traumas, even in presence of bleeding evidence on the CT scan or in the presence of associated lesions [11]. Contrast enhanced computed tomography (CT) scanning is currently the diagnostic imaging tool of choice for the assessment of haemodynamically stable patients thanks to its speed of imaging acquisition, widespread availability, diagnostic accuracy and non invasive characteristics. CT scans can also exclude any simultaneous abdominal injuries requiring surgery, such as bowel or pancreatic lesions. The severity of splenic injury can be decribed with a grading system developed by the American Association of the

Surgery of Trauma (AAST) and it is based on the anatomic disruption of the spleen. However, this grading doesn't adequately consider possible vascular injuries: this could explain why even lower injury grade lesions can lead to hemodynamic instability [12]. Thus, Marmery and colleagues developed a new classification, the Baltimora grading system. This severity index is more complex and takes into account vascular injuries, allowing a direct correlation with vascular CT imaging characteristics and guiding patient clinical management [13]. Since more than 80% of patients with splenic injury trauma are successfully treated with NOM [14], a high AAST grade alone should not be a controindication for NOM. Patient's age, grade of splenic injury, presence/extent of hemoperitoneum, concomitant lesions to other organs and the presence of splenic vascular anomalies or pseudo aneurysms are all factors influencing the success of NOM [15]. As a matter of fact, some patients with high grade splenic lesions without hemodynamic repercussion can be managed with NOM. On the contrary, other patients with haemodynamic instability require urgent surgical intervention, even with low grade injuries. Many studies have shown that vascular lesions are predictive factors for NOM failure [16]. Trauma induced coagulopathy develops in approximately one-third of all patients, with worsened outcomes. Coagulation should be evaluated and corrected as early as possible. The presence of coagulopathy, when a patient is in shock, represents, however, a contraindication for conservative management [17]. Special attention must be paid to elderly patients because they are more likely to take anticoagulants. This may results in delayed haemorrhage and failure of attempts of NOM. The vital parameters on arrival did not influence the risk of NOM failure. The need for red blood cell transfusion to achieve haemodynamic stability could help to identify a group of patients with borderline haemodynamics within the broader group of patients frequently labelled as "responder" to fluid resuscitation. Transfusion rates are higher in patients subjected to Operative Management and they are a risk factor for mortality. In practice, the decision between NOM or OM is mainly driven by haemodynamic considerations rather than the severity of organ injury [18]. Moreover, the clinical decision to perform NOM is influenced by various other factors such as the surgeon's training and experience and available non-physician staff. Currently, NOM is the standard care for haemodynamically stable patients, with an estimated success rate exceeding 80-90 % [19], although there is a direct correlation between the degree of splenic injury and failure rate. Most NOM failures occur within the first 72 hours after admission [20].

NOM decreases the number non therapeutic laparotomies (about 9-14%) with intra abdominal complica-

Table I - *Demographic parameters and post-operative data.*

	2004-2012 (n. 56)	2013-2019 (n. 37)	2004-2019 (n.93)	p
Males	43 (76.7%)	24 (64.8%)	67 (72.0%)	0.069
Operative management (OM)	42 (75%)	11 (29.7%)	53 (57.0%)	<0.001
Non operative management (NOM)	14 (25%)	26 (70.3%)	40 (43.0%)	<0.001
Lenght of hospitalization stay (mean±SD, days)	8.9±3.0	7.4±3.0	7.9±3.0	0.0622
Mortality	5 (8.9%)	3 (8.1%)	8 (8.6%)	0.804
Complications	18 (32.1%)	11 (29.7%)	29 (31.2%)	0.663

Table II - *AAST Spleen Trauma classification.*

Grade	Injury description	
I	Hematoma	Subcapsular, < 10% surface area
	Laceration	Capsular tear, < 1 cm parenchymal depth
II	Hematoma	Subcapsular, 10–50% surface area
		Intraparenchymal, < 5 cm diameter
	Laceration	1–3 cm parenchymal depth not involving a perenchymal vessel
III	Hematoma	Subcapsular, > 50% surface area or expanding
		Ruptured subcapsular or parenchymal hematoma
	Laceration	> 3 cm parenchymal depth or involving trabecular vessels
IV	Laceration	Laceration of segmental or hilar vessels producing major devascularization (> 25% of spleen)
V	Laceration	Completely shatters spleen
	Vascular	Hilar vascular injury which devascularized spleen

tions and unnecessary transfusion risks, consequently reducing overall costs and morbidity and mortality, when compared to OM [21]. As a matter of fact, mortality rate are higher in case of splenectomy, not only in the operating theatre, but above all in the post operative days, due to general complications rather than bleeding. However, no consensus has yet been reached on the correct indications for combining NOM and splenic artery embolisation, especially in higher grade splenic injuries. Splenic embolisation procedure is not free of complications: it increases the risk of haemodynamic deterioration during angiography, late control of haemorrhage, complications of the procedure, and intra abdominal injuries [22].

Patients with intraperitoneal extravasion of costrast material have a higher chance of haemodynamic instability, but not all blushes indicate a need for a splenectomy. Thompson et al evaluated that the size of the contrast blush was correlated with the need for intervention, but actually, cut off values of 1 -1.5 centimetres indicate a need for surgical intervention [23]. Splenectomy must be considered in case of coagulopathy, traumatic brain injury and in patients with multiple other sources of bleeding. Special care must be taken with patients who are receiving systemic anticoagulation therapy and with injured pregnant women who would not tolerate the stress of possible NOM failure. Activity limitation could be a reasonable precaution after NOM, but there is no clear consensus about the time extension.

CT scanning demonstrates apparent healing of all splenic injuries after 6 weeks, while complete healing of almost all grades of splenic lesions is radiologically observed after 3 months [24]. The use of follow up imaging is controversial, without general consensus on the usefulness of repeating the CT scan. In our experience, we only repeat the imaging in cases of high grade injury associated with an active blush on the first radiological investigation, usually 1 month after trauma. Splenic abscess formation is a rare but significant complication that may occur after NOM, while another dreaded complication is late rupture of the spleen, which carries a mortality rate that ranges from 5-15%, compared to a 1% mortality in the case of acute rupture [25].

Extensive scientific evidence has revealed the importance of the immunological role played by the spleen. It has been demonstrated the importance of the mononuclear phagocytes system in fighting infections caused by encapsulated pathogens. Many studies have assessed the increased risk of infection in splenectomy patients, who are particularly susceptible to pneumococcal, meningococcal and Haemophilus infections. The incidence of overwhelming post splenectomy infection is low in the adult population, but the mortality rate exceeds 50% [26]. Vaccinating this population with all three vaccines is the standard of care. The timing of vaccines has been debated but it has been established that pneumococcal vaccination within 24 hours post splenectomy reduces mortality [27]. In our practice, all vaccines are administered within one week post-operatively to balance the need for immune competency with a proper administration.

Limitations

The present study is retrospective and it is based on observation of a group of patients treated in various years, despite the use of a standardized protocol.

Conclusions

NOM has several advantages over OM, including shorter hospital stay and reduced post-operative complications and infections, with a lower economic burden. In case of NOM failure, OM should be considered. Nowadays any blunt splenic trauma could, theoretically, undergo NOM, regardless of the grade of the injury; the only strict criteria for OM should be haemodynamic instability; this assumption depends, of course, on hospital's human and technological resources.

Riassunto

Scopo del Lavoro: Studiare i vantaggi e i potenziali rischi dell'utilizzo del trattamento non operativo dei traumi splenici, allo scopo di dimostrare la possibilità di tale tecnica di diventare il "gold standard" da applicare nel setting di emergenza in pronto soccorso e successivamente in ambiente chirurgico in caso di traumi splenici non penetranti.

Materiali e Metodi: Sono stati valutati retrospettivamente i traumi splenici trattati presso la chirurgia dell'ospedale di Ivrea nel periodo compreso tra il 2004 ed il 2019. Ogni caso è stato classificato all'ammissione presso il dipartimento di emergenza ed accettazione in base alla stabilità del paziente, distinguendo pazienti stabili, instabili e pazienti instabili ma responsivi al trattamento medico; la suddivisione è stata fatta tenendo conto delle linee guida ATLS. Essendo i criteri di esclusione al trattamento non operativo stati pubblicati solamente nel 2013, i dati in nostro possesso sono stati valutati suddividendoli in due tranches a cavallo di tale data.

Risultati: Durante un periodo di 15 anni, circa 6 pazienti per anno sono stati valutati nel nostro pronto soccorso a seguito di un danno splenico. A seguito dell'introduzione del protocollo di gestione non operativa del trauma splenico nel 2013, la proporzione di interventi chirurgici di splenectomia sono andati progressivamente diminuendo, perfino in caso di alti gradi di danno splenico post traumatico. Il numero totale di pazienti sottoposti a trattamento non chirurgico è stato di 40 (circa il 43%) del totale; tenendo invece conto del solo periodo successivo al 2013, il valore totale aumenta a

circa il 70%, dato in linea con la letteratura internazionale attuale.

CONCLUSIONI: Al giorno d'oggi qualunque trauma splenico potrebbe essere, teoricamente, essere sottoposto a trattamento conservativo non chirurgico, indipendentemente dal grado della lesione splenica. L'unica controindicazione stretta al trattamento non operativo risulta infatti essere l'instabilità emodinamica del paziente traumatizzato. La scelta del trattamento non può però ovviamente prescindere dalle risorse umane e tecnologiche dell'ospedale in cui ci si trova a gestire il malato.

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