Clinical Presentation and Management of Pelvic Morel–Lavallee Injury in Obese Patients

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Abstract

Introduction: Morel–Lavallee lesion (MLL) is an infrequent or underreported serious consequence of closed degloving injuries. We aimed to describe the clinical presentation and management of pelvic MLL in obese patients. Materials and Methods: A retrospective analysis was conducted for pelvic trauma patients with a diagnosis of MLL between 2010 and 2012. Patients’ demographics, presentations, management, and outcomes were analyzed and compared based on the body mass index (BMI) and injury severity. Results: Of 580 patients with pelvic region injuries, 183 (31.5%) had MLL with a mean age of 30.1 ± 12.2 years. The majority (75.4%) of MLL patients had a BMI ≥30 and 44% patients had pelvic fracture. Based on the initial clinical examination, MLL was diagnosed in 84% of patients and clinically missed in 16% of patients. Nonoperative management (NOM) was performed in 93.4% of patients, while primary surgical intervention was indicated in 6.6% of patients. Failed NOM was observed in seven cases, of them five were obese. The overall mortality in MLL patients was 12.6% and the frequency of deaths was nonsignificantly higher in Grade I obese patients. Multivariate analysis showed that injury severity score (odds ratio [OR]: 1.25, 95% confidence interval [CI]: 1.05–1.50) and Glasgow coma scale (OR: 0.72, 95% CI: 0.56–0.92) were the predictors of mortality in patients with MLL irrespective of BMI. Conclusions: One-third of pelvic region injuries have MLL and three-quarter of them are obese. This significant association of obesity and MLL needs further prospective evaluation.

Keywords: Degloving, injury, Morel–Lavallee lesion, obesity, pelvis, trauma

Introduction

Morel–Lavallee lesion (MLL) is a challenging and underreported clinical entity with a frequent delay in the diagnosis, particularly in polytrauma patients.[1–5] The definition of MLL was first limited to closed degloving injury around the pelvic girdle, and later on, the term was extended to involve injuries from other anatomic regions.[6,7] However, there is no consistent or definite description of MLL and no clear consensus or guidelines of the modality of management.[7,8] Because of that, there is no clear incidence of this condition in the literature, often missed in up to 44% of cases.[9] This type of injury is relatively rare; it evolves over time; an initial simple contusion can develop into a full-blown case, with time and accumulation of tissue fluids and blood in the degloved area, especially in closed cases; and the diagnosis needs high index of suspicious, thorough physical examination, serial observation, and radiological support.[3] There are no clear criteria, but the literature refers to an area of decreased sensation, soft, bruising, and swelling (hematoma formation). The images that are requested on initial acute presentation of these trauma patients do not report degloving and soft-tissue injuries specifically, and MLL is not within the classic reporting scheme. Moreover, the natural history of progression over time explains the initial trivial changes on admission images such as computed tomography (CT) or magnetic resonance imaging (MRI). The pelvic area is not being well inspected by physicians on their

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daily clinical evaluation unless there is an initial suspicion and documentation is not standards.

Qatar is a small, rapidly developing country characterizes by high motor vehicle crash (MVC)-related injuries with a fatality rate of 23.3/100,000 population as well as high prevalence of obesity (45.4% in men and 38.7% in women). The relation of MLL to obesity has not been described yet. On the assumption that obese patients are more prone to shearing forces by the excess of the mobile soft tissues (lamellar subcutaneous fat) on the underlying relatively fixed fascia around the pelvic girdle (the hypophysis), these prerequisite features of obese patients put them at risk for shearing injury, with accumulation of a hemolympathic collection between these planes, and also for the same reason, they may be prone to more complications, namely, skin necrosis due to paucity of blood supply to the overlying skin by perforators. In this study, we sought to describe the prevalence, clinical presentation, management, and outcomes of MLL based on the patient’s body mass index (BMI).

**Materials and Methods**

This is a descriptive retrospective analysis of a prospectively collected trauma registry from 2010 to 2012 at Hamad General Hospital, the only tertiary level I national trauma center (Hamad Trauma Center [HTC]) in Qatar. The HTC trauma registry is a participant in both the National Trauma Data Bank (NTDB) and the Trauma Quality Improvement Program of the American College of Surgeons and it complies with the standards for data encoding and accuracy of both bodies. The HTC manages around 5000 trauma patients/year; one-third of them necessitate hospital admission and the majority is due to blunt trauma (approximately 90%). Data included patients demographics, mechanism of injury, clinical presentation, associated injuries, BMI, injury severity score (ISS), Glasgow coma scale (GCS), abbreviated injury score (AIS), anatomic location and CT findings, underlying pelvic fractures, and treatment modalities. Hospital and Intensive Care Unit length of stay, ventilatory days, ventilator-associated pneumonia, acute respiratory distress syndrome, sepsis, need for blood transfusion, discharge disposition, and mortality were also reported.

**Definitions**

MLL is a closed internal degloving injury resulted from a trauma of the proximal femur and pelvis as well as lumbar region, where the subcutaneous tissue is torn away from the underlying fascia, creating a cavity filled with hematoma and lymph. The size of these lesions is variable, ranging from small thin slivers of fluid to thickly encapsulated lesions many centimeters in diameter. The diagnosis is based on the clinical findings and reviews of initial imaging often on serial observations during the hospital course and follows up; few cases demanded a radiological confirmation. All charts and radiological studies were carefully reviewed to pick up the cases of MLL and document their incidence, delayed diagnosis, management strategies, responses, and clinical outcome. The presence of area of bruises around the pelvic girdle with decrease sensation plus or minus swelling (hematoma) which needs to be seen later during the hospital course is the clue for diagnosis. An image reporting a significant soft-tissue injury and hematoma (a nonechoic or blood collection with or without septae and solid component superficial to deep fascia around the pelvic girdle) on initial CT scan and on repetition was also included as radiologic diagnosis.

**Degloving injury**

Avulsions or detachment of the skin and subcutaneous tissue from the underlying muscle and fascia secondary to a sudden shearing force applied to the skin surface.

**Obesity**

Patients were grouped as obese (BMI ≥30 kg/m²) and nonobese (BMI <30 kg/m²) group. Obese patients were categorized into Grade I (BMI, 30–34.9 kg/m²), Grade II (BMI, 35–39.9 kg/m²), and Grade III obesity (BMI >40 kg/m²) BMI was calculated using the formula BMI = weight (kg)/(height in m²).

**Inclusion criteria**

All cases admitted to HTC with diagnosis of pelvic injury whether soft tissue and/or fractures of the pelvic bone or femur (upper segment) were included. Patients with incomplete data or clear final diagnosis were excluded.

The primary treatment was defined as an initial conservative or surgical management. Nonoperative management (NOM) included observation, ultrasound-guided aspiration, and pressure dressing. Surgical interventions of MLL involved incision and drainage, debridement, placement of vacuum-assisted closure (VAC), percutaneous management and drainage, and reconstruction plastic surgery. Indications of secondary MLL surgery in case of failure of NOM included large or expanded hematoma, abscess collection, skin necrosis, or secondary closure. Treatment of pelvic fracture was recorded whenever applicable. The current trend among our team is in favor of conservative treatment as these injuries are clean and closed. It is thought to be kept undisturbed for natural resolution process of gradual absorption and fibrosis rather than extensive debridement with potential risk of secondary infection and bleeding and to observe expectantly for excluding rarely reported complications of full-thickness skin necrosis or secondary infection.

**Head injuries**

Traumatic head injuries were defined according to the International Classification of Diseases-9.

We hypothesized that obese patients are at high risk for MLL posttraumatic injuries with a better survival.

This study was conducted in line with the STROBE checklist [Supplementary Table 1]. This study was conducted with the approval of the Medical Research Center (IRB#14013/14) at Hamad Medical Corporation, Qatar.
Statistical analysis
Data were presented as proportions, medians, or mean ± standard deviation, as appropriate. Differences in categorical variables were analyzed using Chi-square test. The continuous variables were analyzed using Student t-test and ANOVA, as appropriate. As we intended to include all pelvic MLL cases, sample size was not calculated. Multivariate logistic regression analysis was performed for the predictors of in-hospital mortality after adjusting for the potential relevant variables (age, obesity, head injury, pelvic fracture, ISS, and GCS). Results were expressed as odds ratios (OR), with accompanying 95% confidence intervals (CIs). P < 0.05 was considered for significant difference. All data analyses were carried out using the Statistical Package for the Social Sciences version 18 (SPSS, Inc., Chicago, IL, USA).

RESULTS
During the study, a total of 580 pelvic injury patients were admitted to the trauma unit, of which 183 (31.5%) were diagnosed with MLL with a mean age of 30.1 ± 12.2 years. The majority of patients were young males (92.3%). The mean BMI of MLL patients was 37.4 ± 10 kg/m². Only 16 patients had normal weight (8.7%) and 29 (15.8%) were overweight. The majority of patients were obese (n = 138; 75.4%) in terms of Grade I (20.2%), Grade II (23.3%), and Grade III (56.5%).

The most frequent mechanisms of injury were traffic-related accidents (51%) and fall from height (36%) [Table 1]. The most commonly associated injuries included abdominal trauma (n = 61%) and chest injury (37%) [Figure 1]. The mean ISS and GCS were 17.8 ± 10.2 and 13 ± 4, respectively. Based on the clinical examination, MLL was diagnosed in 84% of patients and was missed initially in 16%. CT scan examination was needed to confirm the diagnosis in 16.4% cases. Figure 2 shows CT scan images of MLL with left pelvic fracture and hematoma [Figure 2a] and right femur fracture and hematoma [Figure 2b].

The most frequent anatomic location of MLL was lumbar region (44%), femoral head (17.8%), left and bilateral iliac (14.3%), right anterolateral aspect of the pelvis (3.6%), and left upper thigh (3.6%).

Morel–Lavallee lesion management
Blood transfusion was required in 40% of patients with a median of 6 (1–37) units transfused. The majority of patients (n = 171; 93.4%) were initially treated by NOM. Figure 3 shows two examples of the management of MLL.

The primary surgical intervention was required in 12 patients; whereas, secondary surgical intervention was performed in 7 patients who failed the initial NOM [Tables 1 and 2]. Five out of seven patients with failed NOM were morbid obese, Grade III (mean BMI, 45 kg/m²). Incision and drainage with
VAC dressing and debridement (45.5%) was the most frequent primary surgical management. Eighty (43.7%) patients had an underlying pelvic fracture. Surgery for associated pelvic fracture was performed for 13 (16.2%) cases, of which 12 had an internal fixation and 1 had external fixation. The remaining pelvic fracture cases were treated conservatively. Overall, most MLL patients were managed by the trauma team and only 6 were referred to plastic surgery.

One hundred forty (76.5%) patients were discharged home and 14 were transferred to other facilities, including rehabilitation or other hospitals, whereas 23 died during the hospital course. The overall mortality was 12.6%, and in comparison to the NOM group, the surgical group had a trend toward higher mortality (26.3% vs. 11.0%; \( P = 0.05 \)).

Table 3 shows the management and outcome by ISS (low vs. high ISS). The two groups were comparable for age, BMI, pelvic fracture, and management. The mean pelvis AIS was significantly higher in patients with ISS \( \geq 15 \) (2.8 ± 1.0 vs. 2.1 ± 0.3; \( P = 0.001 \)) than patients with less ISS. Furthermore, polytrauma patients had significantly higher rate of mortality (21.7% vs. 0.0%; \( P = 0.001 \)) as compared to nonpolytrauma MLL.

The breakdown and characteristics of MLL patients based on the obesity status is summarized in Table 4. More obese patients with MLL were diagnosed initially by physical examination (87.7% vs. 71.1%; \( P = 0.001 \)) whereas missed clinical diagnosis of MLL was significantly higher in nonobese patients (24.4% vs. 3.6%; \( P = 0.001 \)). The groups did not differ with respect to injury severity. The mortality in obese patients was higher; however, the difference was statistically insignificant (13% vs. 11%; \( P = 0.73 \)).

Table 5 shows the comparison between patients with the Grade I, Grade II, and Grade III obesity. More than half of the obese MLL patients had BMI \( \geq 40 \) (56.5%). Grade III group required significantly higher units of transfused blood (\( P = 0.002 \)). The severity of injury, management, and complications were comparable among the three grades of obesity. The mortality was greater in Grade I, but it did not reach statistical significance.

Multivariate logistic regression analysis showed that the ISS score (OR: 1.25, 95% CI: 1.05–1.50; \( P = 0.01 \)) and GCS (OR: 0.72, 95% CI: 0.56–0.92; \( P = 0.008 \)) were significant predictors of mortality irrespective of BMI [Table 6].

**Discussion**

This is a unique large single-institution report that assesses the clinical presentation and management of MLL in patients...
with a traumatic pelvic injury. The study addresses for the first time the impact of BMI in MLL patients in a small country (1.8 million inhabitants) with a high prevalence of obesity (approximately 33%), and this figure could be underestimated.\cite{11,15,16} The key findings that 31% of pelvic region injury cases had MLL and three-quarter were obese and 44% had pelvic fracture. This relatively high incidence is not reported before as 8% with acetabular fractures, and the incidence of missing these injuries could reach 44%. The high prevalence of severe trauma, traffic-related mode of injury, and associated obesity in our study population may explain in part the high incidence of MLL. The criteria we used to identify these cases may also attribute to the early MLL identification. Moreover, the majority of cases were diagnosed clinically and found that the greater trochanter/hip was the most frequent location of MLL, followed by thigh, pelvis, knee, and gluteal area. Moreover, these lesions are usually present with underlying bone fractures, but might occur in isolation, and are mostly unilateral in nature.\cite{12} MLLs are not necessarily associated with pelvic fractures, as it may also be associated with acetabular fractures or may occur with blunt trauma in the absence of bone fracture.\cite{18}

However, Vanhegan et al.\cite{19} reviewed 29 articles (195 cases) and found that the greater trochanter/hip was the most frequent location of MLL, followed by thigh, pelvis, knee, and gluteal area. Moreover, these lesions are usually present with underlying bone fractures, but might occur in isolation, and are mostly unilateral in nature.\cite{12} MLLs are not necessarily associated with pelvic fractures, as it may also be associated with acetabular fractures or may occur with blunt trauma in the absence of bone fracture.\cite{18}

In the present study, no significant difference was observed for pelvic fracture among obese and nonobese patients which are consistent with the findings of Chuang et al.\cite{20} Moreover, in our study, the severity of injury, management, complications, and mortality were comparable among obese and nonobese patients. Chuang et al. demonstrated that the ISS and mortality did not differ between obese and normal-weight patients.\cite{20} However, these observations in obese MLL patients have not been addressed before and need more scientific exploration to show the exact reason behind the high relationship between obesity and MLL.
Table 4: Comparison between obese and nonobese Morel–Lavallee lesion patients

|                         | Nonobese (BMI <30) (%) | Obese (BMI ≥30) (%) | P  |
|-------------------------|-------------------------|----------------------|----|
| n                       | 45                      | 138                  |    |
| Age (mean±SD)           | 31.1±13                 | 29.8±12              | 0.54|
| Males                   | 42 (93.3)               | 127 (92.0)           | 0.77|
| Method of initial MLL diagnosis |                      |                      |    |
| Clinical diagnosis only | 32 (71.1)               | 121 (87.7)           | 0.001 for all |
| Diagnosis missed on the initial clinical examination* | 11 (24.4)               | 5 (3.6)              |    |
| Cases need confirmation by CT scan | 2 (4.4)               | 12 (8.7)             |    |
| Pelvic fracture         | 23 (51.1)               | 57 (41.3)            | 0.25|
| Head injury             | 8 (17.8)                | 22 (15.9)            | 0.77|
| GCS (ED)                | 12.7±4.5                | 13.2±4.0             | 0.51|
| GCS (ED) <8             | 8 (18.2)                | 18 (13.2)            | 0.42|
| Systolic blood pressure (ED) | 114±26                | 119±25               | 0.19|
| Pelvis AIS              | 2.4±0.8                 | 2.5±0.9              | 0.58|
| Injury severity score   | 18±11                   | 18±10                | 0.69|
| Primary NOM             | 43 (95.6)               | 128 (92.8)           | 0.51|
| Duration of NOM in days | 23 (2-45)              | 26 (5-40)            | 0.50|
| ICU stay                | 3 (1-20)                | 4 (1-36)             | 0.66|
| Total hospital stay in days | 19 (1-90)             | 23 (1-192)           | 0.78|
| VAP                     | 1 (2.2)                 | 7 (5.1)              | 0.39|
| ARDS                    | 0                      | 2 (1.4)              | 0.42|
| Sepsis                  | 0                      | 2 (1.4)              | 0.42|
| Mortality               | 5 (11.1)                | 18 (13)              | 0.73|

*Initially missed on clinical evaluation later diagnosed by CT scan. ED: Emergency department, NOM: Nonoperative management, MLL: Morel–Lavallee lesion, SD: Standard deviation, CT: Computed tomography, GCS: Glasgow coma scale, AIS: Abbreviated injury score, ICU: Intensive Care Unit, VAP: Ventilator-associated pneumonia, ARDS: Acute respiratory distress syndrome, BMI: Body mass index

The clinical signs of MLL can be seen within hours to days posttraumatic event, but in it may remain undiagnosed until radiologically picked up.[1,9,21]

Missed or delayed diagnosis of MLL may occur at the initial presentation.[22] A mild ecchymosis may be challenging to diagnose and may harbor severe lesion that with time will become detectable. Therefore, it is advisable to survey patients frequently, as long as the clinical suspicion persists. A higher frequency of missed diagnosis (44%) of such lesions has been reported by an earlier series of 16 cases.[9]

CT scan is the frequent radiological assessment tool to diagnose well-defined MLL, with encapsulated fluid collection surrounding a mass to confirm the localization and exact size of the lesion.[12,23] However, MRI is the imaging modality of choice to classify MLL types,[3] but is it often impractical to perform MRI for severe trauma patients in the acute care settings.

Management of MLL depends on the stage at which the lesion is detected. It ranges from compression bandage, percutaneous drainage, open debridement, local drainage, sclerotherapy, and extensive hematoma evacuation.[5] Furthermore, lesion size, sterility, fibrous capsule formation, associated injuries, and the age of lesion are additional factors that determine the type of management.

Conservative management remains one of the MLL management options. Conservative treatment with compression dressings has proven to be successful in small, acute MLL.[24] Conservative treatment outcomes are best for those managed acutely.[25] It helps minimize the iatrogenic injury to the subcutaneous vascular supply and improve the overall cosmetic results.[26,27] Small size acute lesions at early stage could be treated by compressive bandage.[28] Harmar et al.[29] suggested treating closed degloving injuries with no excessive fluid accumulation and an intact overlying skin conservatively with compressive bandages or corsets. The signs of healing include disappearing of the fluctuating lesion and loss of excessive skin mobility. Percutaneous drainage can be used to manage larger acute lesions that cannot be resolved with a single application of compression bandages.[30] Few case reports suggested that lesions with delayed diagnosis could be managed conservatively, but these lesions need long-term treatment.[31,32] In our series, lesions missed on initial presentation were also treated conservatively; however, we lack information of the onset and duration of the treatment.

In our study, only 12 patients required primary surgical intervention. Many surgical procedures are described in the literature which include open debridement and VAC dressing application, open debridement with quilting, surgical debridement joined with cutaneofascial suture, or application of synthetic glue.[19,33] Large chronic lesions as well as acute lesions that are associated with other open fractures or had evidence of infection and tissue necrosis should be considered for surgical intervention.[30] Moreover, surgery is indicated in cases with pseudocapsules that are unresponsive to...
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Grade I (BMI 30-34.99) (%) | Grade II (BMI 35-39.99) (%) | Grade III (BMI ≥ 40) (%) | P
---|---|---|---
Grade I (BMI 30-34.99) (%) | 28 (20.3) | 32 (23.2) | 78 (56.5) | 0.16
Age (mean±SD) | 28.7±8.5 | 32.4±11.9 | 29.1±13.1 | 0.18
Males | 26 (93.0) | 27 (84.0) | 74 (95.0) | 0.18
Injury severity score | 18±12 | 18±10 | 17±9 | 0.44
Pelvis AIS | 2.7±0.9 | 2.5±0.9 | 2.4±0.8 | 0.22
Pelvic fractures | 10 (36.0) | 14 (44.0) | 33 (42.0) | 0.79
Conservative management for MLL | 26 (92.9) | 30 (93.8) | 67 (85.9) | 0.39 for all
Surgical treatment for MLL | 2 (7.1) | 2 (6.3) | 6 (7.7) | 0.51
Secondary MLL surgical management | 3 (10.7) | 1 (3.1) | 6 (7.7) | 0.51
Surgical treatment for pelvic fracture | 11 (39.3) | 12 (37.5) | 30 (38.5) | 0.99
Blood transfusion | 10±8 | 5±1 | 12±10 | 0.002
Pneumonia | 2 (7.1) | 1 (3.1) | 4 (5.1) | 0.78
ARDS | 1 (3.6) | 0 | 1 (1.3) | 0.50
Sepsis | 0 | 0 | 2 (2.6) | 0.46
Hospital length of stay | 22 (1-81) | 23 (1-192) | 23 (1-132) | 0.62
ICU length of stay | 3 (1-24) | 3.5 (1-36) | 4 (1-22) | 0.61
Mortality | 5 (17.9) | 3 (9.4) | 10 (12.8) | 0.62

AIS: Abbreviated injury score, ICU: Intensive Care Unit, SD: Standard deviation, MLL: Morel–Lavallee lesion, ARDS: Acute respiratory distress syndrome, BMI: Body mass index

Two-thirds of the patients were diagnosed with MLL during the initial presentation and were successfully treated nonoperatively. Patients were referred to our institution for pelvic fracture and further workup of MLL. In our series, one of three patients with skin necrosis underwent skin grafting. The  

Emergency physicians and radiologists should be familiar with the clinical and radiological characteristics of MLL earlier to avoid confusion with tumors or hematomas. Therefore, early diagnosis and management of the lesion is essential to prevent infectious complications and extensive skin necrosis. The overall mortality in our series was 12.6%, and ISS and GCS were found to be an independent predictor of mortality in patients with MLL regardless of BMI.

**Limitations**

The data were collected retrospectively from the records of our institute database registry which included surgeons' identification, diagnosis, and management of MLLs during the study. The sample size was not specified before the study. Furthermore, the time needed to MLL to evolve after injury was not given. The exact information of the types of MLL is lacking as MRI imaging was not performed. It was not clear in this retrospective analysis that how different were the size of lesion and technique of NOM in obese and nonobese MLL patients. The anatomic location, size, and extent of lesions were not completely available. It has been suggested that MLL is a potential risk for surgical site infection (SSI) in patients with acetabular fracture. In our study, we lack information regarding SSI in cases that underwent surgical treatment for a pelvic fracture. Furthermore, we relied on BMI and not the central obesity which could be a limiting factor of accurate estimation of the definition and impact of obesity. The frequency of obesity in non-MLL was not shown in the database. Clinical follow-up data were lacking. The prevalence of obesity is high and suggests a coexisting with or simple association rather than causation. There are different grades of degloving injury, and consensus diagnostic criteria and grading are needed to help reporting these lesions and inform the clinical management decisions.

**Conclusions**

One-third of pelvic region injury cases were diagnosed with MLL. Majority of cases were diagnosed clinically with acute presentation and were successfully treated nonoperatively. We recommend a regular clinical evaluation to analyze missed
lesion during the initial course of admission. Interestingly, 75% of MLL cases were obese, a finding that needs further workup to know the exact mechanism and implications for this association. However, apart from the initial failure of NOM in few cases, obesity has no substantial impact on the hospital course if injuries are well treated before complications take place. Factors that could explain the success of conservative treatment in the majority of our series need further evaluation.

**Ethical approval**

This retrospective analysis with no direct contact with participants and data were collected anonymously. Therefore, the medical research center granted a waiver of consent. This study was conducted with the approval of the Medical Research Center at Hamad Medical Corporation (IRB/#14013/14), Doha, Qatar.

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Nil.

**Conflicts of interest**

There are no conflicts of interest.

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Supplementary Table 1: STROBE statement – checklist of items that should be included in reports of observational studies

| Item number | Recommendation                                                                 | Page |
|-------------|-------------------------------------------------------------------------------|------|
| Title and abstract | (a) Indicate the study design with a commonly used terms in the title or the abstract. | 1 |
| | (b) Provide in the abstract an informative and balanced summary of what was done and what was found. | 2-3 |
| Introduction | | 3-4 |
| Background/rationale | Explain the scientific background and rationale for the investigation being reported. | 3 |
| Objectives | State-specific objectives, including any prespecified hypotheses. | 6 |
| Methods | | 4-6 |
| Study design | Present key elements of study design early in the paper. | 4 |
| Setting | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection. | 4-6 |
| Participants | (a) Cohort study – Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up. | 4-5 |
| | Case–control study – Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls. | 4-5 |
| | Cross-sectional study – Give the eligibility criteria, and the sources and methods of selection of participants. | 4-5 |
| | (b) Cohort study – For matched studies, give matching criteria and number of exposed and unexposed. | 4-5 |
| | Case–control study – For matched studies, give matching criteria and the number of controls per case. | 4-5 |
| Variables | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable. | 4-6 |
| Data sources/measurement | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. | 4-5 |
| Bias | Describe any efforts to address potential sources of bias. | Page 3 and Table 6 |
| Study size | Explain how the study size was arrived at. | 13 |
| Quantitative variables | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why. | 5 |
| Statistical methods | (a) Describe all statistical methods, including those used to control for confounding. | 6 |
| | (b) Describe any methods used to examine subgroups and interactions. | 6 |
| | (c) Explain how missing data were addressed. | 6 |
| | (d) Cohort study – If applicable, explain how loss to follow-up was addressed. | 6 |
| | Case–control study – If applicable, explain how matching of cases and controls was addressed. | 6 |
| | Cross-sectional study – If applicable, describe analytical methods taking account of sampling strategy. | 6 |
| | (e) Describe any sensitivity analyses. | 6 |
| Results | (a) Report numbers of individuals at each stage of study – e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed. | 6-8 |
| | (b) Give reasons for nonparticipation at each stage. | 6-8 |
| | (c) Consider use of a flow diagram. | 6-8 |
| Descriptive data | (a) Give characteristics of study participants (e.g., demographic, clinical, and social) and information on exposures and potential confounders. | 6 |
| | (b) Indicate number of participants with missing data for each variable of interest. | 6 |
| | (c) Cohort study – Summarize follow-up time (e.g., average and total amount). | 6 |
| Outcome data | Cohort study – Report numbers of outcome events or summary measures over time. | 7-8 |
| | Case–control study – Report numbers in each exposure category or summary measures of exposure. | 7-8 |
| | Cross-sectional study – Report numbers of outcome events or summary measures. | 7-8 |
| Main results | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included. | 6-8 |

Contd...
### Supplementary Table 1: Contd...

| Item number | Recommendation | Page |
|-------------|----------------|------|
| Other analyses | (b) Report category boundaries when continuous variables were categorized  
(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful period  
Report other analyses done – e.g., analyses of subgroups and interactions and sensitivity analyses | 9-13 |

| Discussion | Key results | Limitations | Interpretation | Generalizability | Other information |
|------------|------------|-------------|----------------|------------------|------------------|
| 17 | Summarize key results with reference to study objectives | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | Discuss the generalizability (external validity) of the study results | 9-13 |

| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 15 |

Information on the STROBE Initiative is available at www.strobe-statement.org