UNIVERSIDADE FEDERAL DE SERGIPE

CENTRO DE CIÊNCIAS BIOLÓGICAS E SAÚDE

DEPARTAMENTO DE MEDICINA

FILIPE EMANUEL FONSECA MENEZES

SEMELHANÇAS E DIFERENÇAS ENTRE OS CRITÉRIOS DA OMS E OUTROS DOIS PARA DIAGNÓSTICO DE *NEAR MISS* MATERNO

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AGRADECIMENTOS

Aos meus pais, Antonio Jorge e Ana Maria, meus maiores apoiadores em todos os momentos incondicionalmente. Obrigado por fazerem de tudo para me verem feliz. Ao meu irmão Danilo Henrique, pela amizade, compreensão, sugestões de estudo, conversas e apoio. Farei de tudo para também vê-los felizes. Amo vocês!

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LISTA DE TABELAS E FIGURAS

REVISÃO BIBLIOGRÁFICA

ARTIGO CIENTÍFICO

LISTA DE ABREVIATURAS E SIGLAS

REVISÃO BIBLIOGRÁFICA

- MMG: mortalidade materna grave
- NM: *near miss* materno
- OMS: Organização Mundial de Saúde

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- ICU: Intensive care unit
- LB: Live births
- MD: Maternal deaths
- MNM: Maternal near Miss
- PPV: Positive predictive value
- WHO: World Health Organization

SUMÁRIO

I. REVISÃO DA LITERATURA

1. Introdução

No ano 2000 as Nações Unidas definiram oito Objetivos do Milênio a serem atingidos até 2015, incluindo, entre eles, o 5° objetivo tratando da melhoria da saúde materna. Para alcançar tal objetivo foram definidos dois pontos principais: reduzir em três quartos a taxa de mortalidade materna e alcançar acesso universal para a saúde reprodutiva (LOMAZZI; BORISCH; LAASER, 2014).

Dados da Organização Mundial de Saúde (OMS) trazem avanços, estimam-se 543.000 mortes maternas em 1990 e 289.000 em 2013, com um declínio de 45% no período. A taxa de mortes maternas pelo número de nascidos vivos, definida como coeficiente ou taxa de mortalidade materna, reduziu de 310 para 210 para cada 100.000 nascidos vivos em 183 países, entre os anos de 1990 e 2013. No entanto, esses números ainda estão longe da redução de 75% pretendida pela OMS para 2015, portanto, apesar dos avanços, dificilmente será alcançado como desejado o quinto Objetivo do Milênio mundialmente (WORLD HEALTH ORGANIZATION, 2014).

Das mortes maternas, 286.000 (99%) ocorreram em países em desenvolvimento, sendo a maioria, na África Sub-Saariana (179.000) e sul da Ásia (69.000). A taxa de mortalidade materna é 14 vezes maior comparando países em desenvolvimento em relação aos países desenvolvidos (WORLD HEALTH ORGANIZATION, 2014). No Brasil em 1990 a taxa de mortalidade materna foi de 120 para cada 100.000 nascidos vivos e em 2013 foi de 69, uma queda de 2,4% ao

ano, abaixo do 5° Objetivo do Milênio que definia 5,5% ao ano como alvo (UNITED NATIONS, 2014; WORLD HEALTH ORGANIZATION, 2013).

No relatório da OMS sobre as tendências em mortalidade materna 2010-2013, ressaltaram-se a necessidade de melhorias na disponibilidade e qualidade das análises sobre saúde materna como uma importante ferramenta para captar essas mortes maternas, estimar a mortalidade materna e, consequentemente, melhorar o atendimento em saúde materna e a prevenção de novas mortes maternas (WORLD HEALTH ORGANIZATION, 2014).

Com o objetivo de melhorar a saúde materna, várias definições e índices são usados e estudados para mesurar cada vez melhor a saúde materna em todo o mundo, entre eles o estudo do conceito de mortalidade materna grave (MMG) e *near miss* materno (NM).

2. Mortalidade materna e *Near Miss* materno

Uma das estratégias nos estudos de saúde materna é utilizando definições largamente reconhecidas e indicadores para monitorar o cuidado obstétrico.

O CID-10, classificação internacional de doenças e problemas de saúde 10ª edição define morte materna como:

> "a morte materna de uma mulher durante a gravidez ou dentro dos 42 dias ao final da gravidez, independente da duração ou local da gravidez, de qualquer causa relacionada ou agravada pela gravidez ou seu acompanhamento, mas não de causas acidentais ou incidentais." (HUGHES, 2011)

O estudo de casos de MMG e NM, casos de mulheres com sérias complicações e que quase morreram durante a gravidez ou parto, é considerado por

muitos autores como uma dessas estratégias importantes para reduzir as mortes maternas (SAY; SOUZA; PATTINSON, 2009; TUNÇALP et al., 2012).

O termo *near miss* é um termo originário da aviação e aplicado a diversas situações na prática clínica, sendo algo com potencial de causar algum tipo de lesão ou dano, mas não o faz. (NASHEF, 2003)

No âmbito do cuidado à mulher ele é adaptado como *near miss* materno, sendo definido pela Organização Mundial de Saúde como: ‘’a mulher que quase morreu, mas sobreviveu a uma complicação que ocorreu durante a gravidez, o parto ou dentro dos 42 dias de término da gravidez’’ (SAY; SOUZA; PATTINSON, 2009).

A vantagem de se estudar casos de NM é que eles possuem várias características em comum com as mortes maternas. E também são mais frequentes de encontrarmos casos de MMG e NM em relação aos de mortes maternas (RONSMANS, 2009; SAY; SOUZA; PATTINSON, 2009). Desse modo seria possível intervir de maneira a melhorar a qualidade da atenção obstétrica.

3. Classificações de mortalidade materna grave e *Near Miss* Materno

Seguindo o objetivo de melhorar a atenção às mulheres, diversos estudiosos buscaram definir critérios para selecionar os casos de MMG e NM. Eles definiam critérios baseados nos sinais e sintomas clínicos, disfunção orgânica e sistêmica, presença ou não de determinadas patologias e manejo ou intervenções sobre o paciente.(REICHENHEIM et al., 2009; RONSMANS, 2009; SAY; PATTINSON; GÜLMEZOGLU, 2004; SAY; SOUZA; PATTINSON, 2009).

Abaixo estão destacados alguns desses importantes estudos e os critérios para a seleção de casos maternos graves:

Em 2001, foi publicado um estudo caso-controle realizado em 19 maternidades do Reino Unido entre março de 1997 e fevereiro de 1998. Nele foram definidos 6 critérios para MMG/NM baseados em dados clínicos e síndromes obstétricas bem definidas (Tabela 2) (WATERSTONE; BEWLEY; WOLFE, 2001).

O estudo também ressaltou que múltiplas definições para morbidade materna grave são utilizadas. E identificou como principais fatores de risco para morbidade materna: idade acima de 34 anos, exclusão social, não brancos, hipertensão, hemorragia pós-parto prévia, indução de parto e parto cesáreo. Dos casos de seu estudo dois terços estavam relacionados a desordens hemorrágicas e um terço a desordens hipertensivas (WATERSTONE; BEWLEY; WOLFE, 2001).

Em revisão sistemática de 2009, foram avaliados diversos estudos sobre morbidades maternas graves e os critérios quantitativos e qualitativos utilizados para definir um caso de NM. O objetivo foi contribuir com um mecanismo mais adequado para busca estes casos. Ao final, definiram 13 critérios baseados em revisão da literatura para seu diagnóstico (Tabela 3). (REICHENHEIM et al., 2009).

Alguns critérios foram deixados de fora por falta de uma definição clara e outros por estarem relacionadas a condições pouco comuns. Eles também sugeriram a necessidade de outros estudos para testar a sensibilidade e especificidade dos seus critérios (REICHENHEIM et al., 2009).

Diversos outros estudiosos dedicaram seu tempo para aprofundar o assunto como, por exemplo, Mantel et al. (1998) e Geller et al. (2004) definiram diferentes abordagens para classificar e estudar os casos de quase morte materna. A variedade de critérios e classificações para caracterizar os casos de NM foi ressaltada em revisões sistemáticas por diversos autores (LOTUFO et al., 2012; RONSMANS, 2009; SAY; SOUZA; PATTINSON, 2009; SOUZA et al., 2006). A

multiplicidade de critérios dificultava a comparação entre os estudos e o avanço na melhoria do cuidado materno baseado em evidências.

Diante do exposto, em 2009, foi publicada uma abordagem sobre a mortalidade materna através da análise do grupo de trabalho em classificações de Mortalidade e Morbidade Materna da OMS (SAY; SOUZA; PATTINSON, 2009). Nele foram analisados os critérios utilizados até então em diversos estudos e quais eram suas vantagens e desvantagens, pois a falta de uma definição com critérios bem esclarecidos para identificação de MMG/NM dificultava os estudos e tornava difícil a comparação entre eles.

O grupo de trabalho da OMS criou organogramas para facilitar o estudo de mortalidade e morbidade materna grave através de critérios que fossem viáveis para comparação entre instituições durante o tempo e viável também para uso independentemente do nível de desenvolvimento, até mesmo em lugares em que tecnologia e laboratórios avançados não são disponíveis. Os critérios de NM da OMS incluem critérios clínicos, baseados em alterações laboratoriais e procedimentos (Tabela 1).

4. Avaliação e validação dos critérios para *near miss* da OMS

Com a padronização dos critérios de NM pelo grupo de trabalho da OMS, foram realizados diversos estudos para validá-lo. E também para avaliar casos de morbidade e mortalidade materna em diversos cenários, principalmente naqueles com poucos recursos e onde a maioria dos casos ocorrem, como países da África e da Ásia (SAY; SOUZA; PATTINSON, 2009; SPECTOR, 2013; WORLD HEALTH ORGANIZATION, 2011).

Estudos realizados no Brasil e no Canadá validaram os critérios para NM baseados em dados laboratoriais e em procedimentos da OMS. Encontrou-se sensibilidade de 100% e especificidade acima de 90%, ou seja, os critérios da OMS foram capazes de identificar todos os casos de morte materna (CECATTI et al., 2011; NELISSEN et al., 2013; SOUZA et al., 2012).

Cecatti et al. (2011) avaliaram a capacidade dos critérios da OMS identificar casos de NM e mortes maternas entre os casos de Mortalidade Materna Grave em pacientes admitidos em uma UTI e também comparou os NM pela OMS com o score agregado de falência orgânica, o SOFA – Score de abordagem sequencial para falência orgânica. Os critérios da OMS identificaram todos os casos de morte materna e quase todos de falência orgânica.

A padronização dos critérios para NM pela OMS foi um avanço diante da multiplicidade de definições de NM que dificultavam a comparação entre os estudos existentes, entretanto os critérios da OMS ainda tem suas limitações e diversos autores ressaltaram a necessidade de sua adaptação a depender do local utilizado (NELISSEN et al., 2013; SPECTOR, 2013). Por exemplo, Nelissen et al (2013) teve de adaptar os critérios da OMS pela dificuldade em usar os critérios baseados em dados laboratoriais. Novos estudos e adaptações dos critérios da OMS podem ser necessários para otimizar a atenção a saúde materna (SPECTOR, 2013; WORLD HEALTH ORGANIZATION, 2011).

5. Anexos

Tabela 1. Critérios para classificação de *near miss* materno pela OMS

Critérios Clínicos
Cianose aguda
Gasping
Frequência Respiratória >40 ou <6/min
Choque
Oligúria não responsiva a administração de fluidos ou diuréticos
Falência da coagulação
Perda de consciência por período ≥ 12 horas
Perda de consciência e falta de pulso / frequência cardíaca
Acidente vascular cerebral (AVC)
Paralisia total
Icterícia na presença de pré eclampsia
Critérios baseados em alterações laboratoriais
Saturação de Oxigênio <90% por ≥ 60 minutes
pH < 7.1
PaO2/FiO2 < 200 mmHg
Lactato > 5
Creatinina ≥ 300 μmol/l ou ≥ 3,5 mg/dl
Trombocitopenia aguda (<50.000 plaquetas)
Bilirubina >100 μmol/l ou > 6,0 mg/dl
Perda de consciência e presença de glicose e corpos cetônicos na urina
Critérios baseados na realização de procedimentos invasivos
Uso contínuo de drogas vasoativas
Intubação e ventilação por período ≥ 60 minutos não relacionado à anestesia
Histerectomia por infecção ou hemorragia
Diálise por falência renal aguda
Transfusão de CINCO unidades ou mais de concentrado de hemáceas
Ressucitação cardio-pulmonar

Fonte: (SAY; SOUZA; PATTINSON, 2009)

Tabela 2. Critérios de n*ear miss* materno por Waterstone

Pré-eclampsia grave
Eclampsia
Síndrome HELLP
Hemorragia grave
Sepse grave
Ruptura uterina

Fonte: (WATERSTONE; BEWLEY; WOLFE, 2001).

Tabela 3. Critérios de n*ear miss* materno baseados na literatura

Eclampsia
Hipertensão grave
Edema pulmonar Edema pulmonar
Parada cardíaca
Hemorragia obstétrica
Ruptura uterina
Admissão em unidade de terapia intensiva
Histerectomia de emergência
Transfusão sanguínea
Complicações ou acidentes anestésicos
Uréia > 15 mmol/l ou creatinina > 400 mmol/l
Oliguria (<400ml/24h)
Coma

Fonte: (REICHENHEIM et al., 2009)

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Tropical Medicine & International Health

Similarities and differences between WHO criteria and two other approaches for maternal near miss diagnosis

Short title: Evaluation of three different approaches of maternal near miss diagnosis

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Abstract

Objectives: To evaluate the similarities, differences and diagnostic aspects between World Health Organization (WHO) criteria and two other maternal near miss (MNM) diagnostic tools.

Methods: A cross-sectional study was conducted from June-2011 to May-2012 in two reference maternity hospitals in Aracaju, Brazil. Prospective case identification and data collection was performed and female patients were classified as an MNM case according to WHO, Waterstone and literature-based criteria. The diagnostic properties and concordance of literature-based and Waterstone criteria were calculated using WHO criteria as standard.

Results: From a total of 20,435 patients, 19,239 women did not have potentially life-threatening conditions, there were 17 maternal deaths and 77 MNM cases based on the WHO criteria. Waterstone and literature-based criteria identified 404 and 959 MNM cases, respectively; most of them related to hypertensive disorders and haemorrhage. The sensitivity, specificity and accuracy in diagnosing MNM cases using Waterstone and literature-based criteria were above 90%, but Waterstone sensitivity was 48.1%. The similarities between the Waterstone and literature based criteria were very weak compared to WHO criteria, with a positive percentage concordance of below 9%.

Conclusions: Although using WHO guidelines to detect MNM cases can be difficult when implemented in low-resource settings, the results from this study reinforce the importance of this tool in detecting the truly severe cases. Waterstone and literature-based criteria are not suitable for identifying indubitable MNM. However, they are still useful as a preliminary step to select potentially severe cases, mainly those related to hypertension and haemorrhage.

Key words: Maternal near miss; maternal health; maternal severe cases; severe maternal morbidity.

Introduction

In 2000, the World Health Organization (WHO) defined eight millennium goals to be achieved by 2015, including global maternal health improvement (5^{th} goal). To reach this goal, two priorities were suggested: reduce maternal mortality by 75% and achieve universal access to reproductive healthcare [1].

In 2013, approximately 290,000 maternal deaths occurred globally. The majority of these cases occurred in low and middle-income countries, where the maternal mortality ratio (MMR) can be 14 times greater than in high-income countries [2]. Despite significant advances, there is still a need to improve the availability and quality of analysis with regard to maternal health in order to reduce maternal mortality.

MNM cases account for most of the characteristics of maternal death (MD), they occur at least three times more frequently and MNM occurs immediately before MD [3]. In 2009, after years without consensus with regard to the definition and criteria for MNM, the WHO defined it in an attempt to promote and standardise the concept of the condition [4]. A patient is considered to have experienced MNM when she nearly died, but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy.

Previously, Waterstone criteria considered clinical data and obstetric syndromes that could be measured routinely. The listed criteria were: severe preeclampsia, eclampsia, HELLP syndrome, severe sepsis and uterine rupture [5]. Reichenheim et al., through a systematic review of the most commonly used literature criteria, compiled a list of 13 literature-based criteria that are easy to apply and effective in searching for MNM cases [6]. Both classifications are useful in low and middle-income settings.

Despite the current recommendations for the use of WHO criteria [4,7], some authors state that this is not feasible for low-resource settings where the application of laboratory-based and management-based criteria is limited [8–11]. In a previous study, we presented the prevalence

of pottentially life threatening conditions and maternal near miss; in this study we evaluated the similarities and differences between Waterstone, literature-based and WHO criteria for MNM, using the latter as the reference criteria.

Methods

A cross-sectional study was performed to identify MNN situations in women during pregnancy, childbirth or postpartum up to 42 days in two reference maternity hospitals in Sergipe state, Northeast-Brazil, between June 2011 and May 2012.

The two maternity hospitals are the main public reference hospitals for Sergipe state: Nossa Senhora de Lourdes Maternity and Santa Isabel Hospital. The former performs approximately 400 deliveries per month and is responsible for the high-risk deliveries. The latter is responsible for 950 deliveries per month and covers low and medium obstetric risk patients; it is the only one equipped with an obstetric intensive care unit (ICU).

Every 48 hours, an obstetrician specialising in maternal morbidity performed an active search in the two hospitals to identify potentially life-threatening conditions as a starting point (Table 1) [4]. Using this information, we would then identify all significant morbidity they could have for the three classification methods (Figure 1). This comprised a medical visit with patients every 48 hours in all sectors including admission, pre and post labouring wards, ICU, surgical theatres and delivery rooms. Extra checks were performed with regard to the medical records (in case of doubt or to confirm some MNM laboratory parameters) and in the blood bank register book. These extra checks were systemic during the study period. Each sector of the hospitals had a map of patients including the diagnostic that was updated every day, so all patients interned were monitored in case they developed a potential MNM situation.

Following this, four trained medical students classified patients as a MNM case or not according to three different diagnostic approaches: WHO, Waterstone and literature-based

(Table 2). Another researcher resolved disagreements. Patients who were admitted twice were included in the study only once and cases culminating in death were excluded. All listed situations by the two other approaches are included in the potentially life threatening conditions or as a MNM case, so no case was missed, the woman was classified in one-way or another.

Detailed methodology is described in a previous study of prevalence using the same population [11].

Both Waterstone and literature-based criteria were chosen from the literature because they were better for recognizing a case as an MNM case (based on clinical parameters), an important characteristic for low-resource income settings.

Data Analysis

Categorical variables were described using frequencies and percentages. Using the WHO criteria as a reference standard, the diagnostic properties of the Waterstone and literature-based criteria were calculated using binomial exact methods. The MNM incidence ratio (MNM-IR) was calculated as the number of MNM/1,000 live births (LB) for the three different approaches [4].

The agreement between the three instruments was also calculated using the positive percentage concordance, which is adopted for studies with a low prevalence of variables, such as MNM [12]. The Kappa test was applied to evaluate the concordance results. Kappa values and interpretations in this study were: < 0 (no agreement), from 0 to 0.19 (very weak agreement), from 0.20 to 0.39 (weak agreement), from 0.40 to 0.59 (moderate agreement), 0.60 to 0.79 (substantial agreement) and 0.8-1.0 (excellent agreement) [13].

The significance level used for all analyses was 5% ($p < 0.05$). The analyses were performed using SPSS software version 20.0 (IBM Corporation, Armonk, New York, USA) and Epi Info

7 (CDC, Atlanta, GA, USA). This study was reviewed according to the STARD statement [14].

Ethics consideration

The study was approved by the Human Research Ethics Committee of the Federal University of Sergipe (Protocol number 0184.0.107.000-11). All investigation was conducted according to the Declaration of Helsinki. We reviewed the charts to detect potentially life-threatening conditions and, for these women, written informed consent was obtained. For a previous study on prevalence of MNM in this population, a questionnaire was performed and occasionally this information can be valuable when classifying a patient as MNM.

Results

During the study period, a total of 20,435 patients were admitted. From those, 1,196 cases presented potentially life-threatening conditions, including 17 maternal deaths. A total of 964 cases were classified as presenting with an MNM situation according to at least one of the three MNM diagnostic groups. The WHO criteria classified 77 cases of MNM and the Waterstone criteria and the literature-based criteria detected 404 and 959 cases, respectively. From all the admissions, 19,239 women did not present with potentially life-threatening conditions.

The Venn diagram in Figure 2 represents the relationship between the three MNM diagnostic approaches. From the 77 MNM cases identified by WHO criteria, 72 were also detected by the literature-based criteria and 37 by the Waterstone criteria. Four patients (5.2%) were detected exclusively by the WHO criteria and they were eligible according to four different components.

From the 959 cases identified by the literature-based criteria, we detected the following eligible criteria: 596 (54.8%) for severe hypertension, 308 (28.3%) for blood transfusion, 82

(7.5%) for ICU admission, 56 (5.1%) for eclampsia, 19 (1.7%) for emergent hysterectomy, 8 (0.7%) for obstetrical haemorrhage, 5 (0.5%) for oliguria, 4 (0.4%) for anaesthetic accidents or complications, 3 (0.3%) for cardiac arrest, 2 (0.2%) for pulmonary edema, 2 (0.2%) by urea > 15 μmol or creatinina > 40 μmol, 2 (0.2%) for uterine rupture and 1 (0.1%) for coma.

The Waterstone criteria identified 404 MNN cases: 308 (71.6%) for severe preeclampsia, 56 (13%) for eclampsia, 34 (7.9%) for HELLP syndrome, 26 (6%) for severe haemorrhage, 4 (0.9%) for severe sepsis and 2 (0.5%) for uterine rupture.

Based on the 16,243 live births in the studied maternity hospitals, the MNM-IR for the WHO criteria was 4.7 cases/1,000 LB, for the Waterstone criteria was 24.8/1,000 LB and for the literature-based criteria 59/1,000 LB. The sensitivity, specificity, positive predictive and negative predictive value to diagnose MNM cases using the Waterstone and literature-based criteria are shown in Table 2.

Analysis of the similarities between the WHO and Waterstone criteria showed a positive percentage concordance of 8.3% (37/444), which was considered very weak (kappa = 0.15, p = 0.04). Moreover, the similarities between the WHO and literature-based criteria demonstrated a positive percentage concordance of 7.4% (72/964), which was also considered very weak (kappa = 0.13, p = 0.03; Table 3).

Discussion

The WHO highlights the need for change in order to achieve the goal of reducing maternal and neonatal morbidity and mortality [2,9]. The study of MNM cases has proven effective in understanding the reasons underlying female deaths in childbirth [2]. We believe that all medical services need to improve the quality of maternal care worldwide, particularly in the low/middle income countries, and MNM cases may be a powerful way to recognize their own

deficiencies. From there, changes may be proposed and comparisons made between different health services (using the same set of criteria).

The prevalence of MNM varies widely and depends on the diagnostic approach used [3,15,16]. This study demonstrated this variation by using three different diagnostic tools: both the literature-based criteria and the Waterstone criteria detected more cases of MNM than the reference criteria (WHO), finding twelve times more and five times more cases, respectively.

The literature-based and Waterstone criteria tended to detect more cases with less severity, while the WHO criteria tended to detect the more severe cases and those cases immediately prior to death. This might be explained by the fact that the literature-based approach has weak and wide-ranging eligibility criteria. It allows women with both mild hypertension and those who received only one blood bag to be classified as MNM cases. Delivery is a condition that causes considerable blood loss even in regular situations and the literature-based classification neither defines the level of hypertension nor the number of blood bags transfused. The Waterstone criteria also detected all women with preeclampsia as MNM cases whereas the WHO criteria only include these patients in the presence of jaundice. In general, the WHO criteria focus on severe cases and eliminates situations with borderline severity. Hypertension in pregnancy and severe haemorrhage are manageable risk factors associated with maternal morbidities, as demonstrated by many authors [3,5,17–19]. The detection of those morbidities may still be useful in some scenarios.

The low positive predictive value obtained in this study reinforces the hypothesis that the literature-based or Waterstone criteria are inadequate for detecting severe cases of MNM. If the objective is to detect potentially life-threatening conditions in low-resource settings, then these two classification tools may be acceptable as they are easy to use. The low positive percentage agreement associated with a low Kappa for both literature-based and Waterstone

diagnostic tools is explained by the great number of cases that the two methods identify. This weak agreement reemphasises the need for all maternal care services to adopt the WHO approach as the standard method to classify a patient as an MNM case [4,7,20]. This measure will help to avoid cases of maternal death that occur every day in the poorest regions of the world.

Diagnostic techniques with high sensitivity and specificity would be ideal complements to the WHO criteria. The literature-based criteria showed high sensitivity and specificity, and despite having heterogeneous and not well-defined criteria, served as background for selection of severe maternal cases. The Waterstone criteria showed low sensitivity suggesting that, when used in association with WHO criteria, it should be adapted to avoid losing real cases of MNM.

The main limitation of the study was the difficulty in classifying patients as MNM cases using the WHO criteria. This is a limited classification for low-resource settings. This occurred due to structural deficiencies in the health service, in particular, the absence of an ICU in the high-risk maternity hospital, the lack of some therapeutic resources and laboratory parameters and the loss of information due to incomplete medical records.

Finally, is urgent and necessary that low and middle-income countries implement a risk evaluation system such as the WHO classification. To understand the risk factors for maternal deaths and to improve the obstetric care it is necessary to consider the different needs of each health service. It is important to point out that this is a complex classification to apply in places that have problems with primary care and we believe that some adjustments are necessary in order to make the tool efficient. One example is the proposed adjustment to the new WHO/MNM guidelines for quality of care for severe pregnancy complications published in 2011: this recommended a broader set of criteria, including use of blood products, severe pre-eclampsia and others [21]. We think that the literature-based and the Waterstone

approaches could still be useful in certain scenarios where hypertensive disorders and severe haemorrhage are prevalent and related to maternal deaths for the simplicity of classification. Prospectively, since the WHO is the currently adopted classification system for MNM, a simplified form must be designed to reach the goal: find cases where they occur most frequently in order to save lives.

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List of figures

List of tables

Figure 1: Method of screening of patients with maternal near miss for the three diagnostic approaches in the two selected maternities.

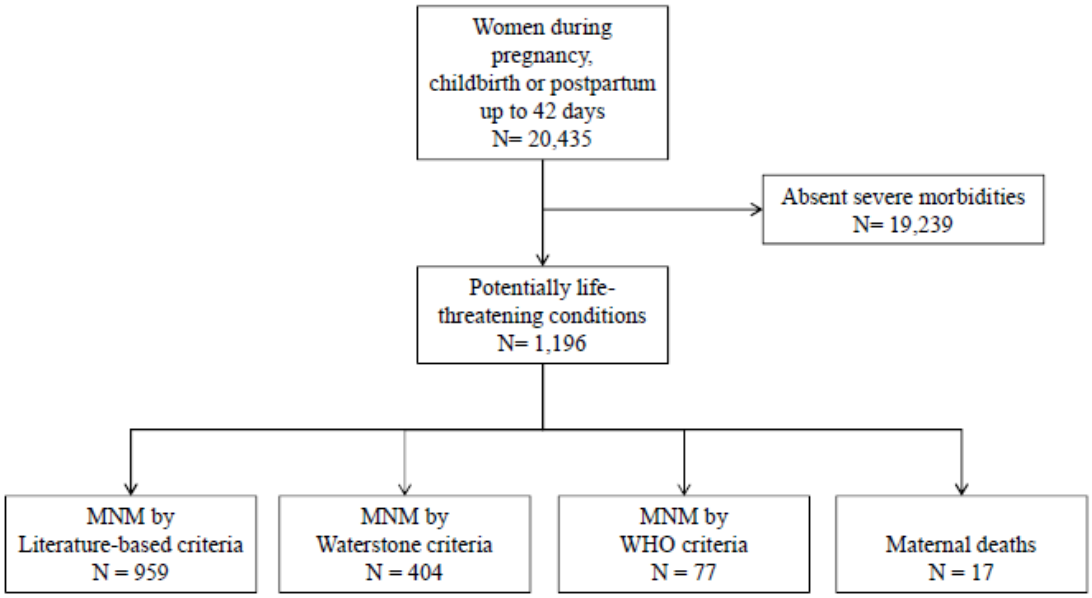

Figure 2: Maternal near miss outcomes according WHO, Waterstone and literature-based criteria.

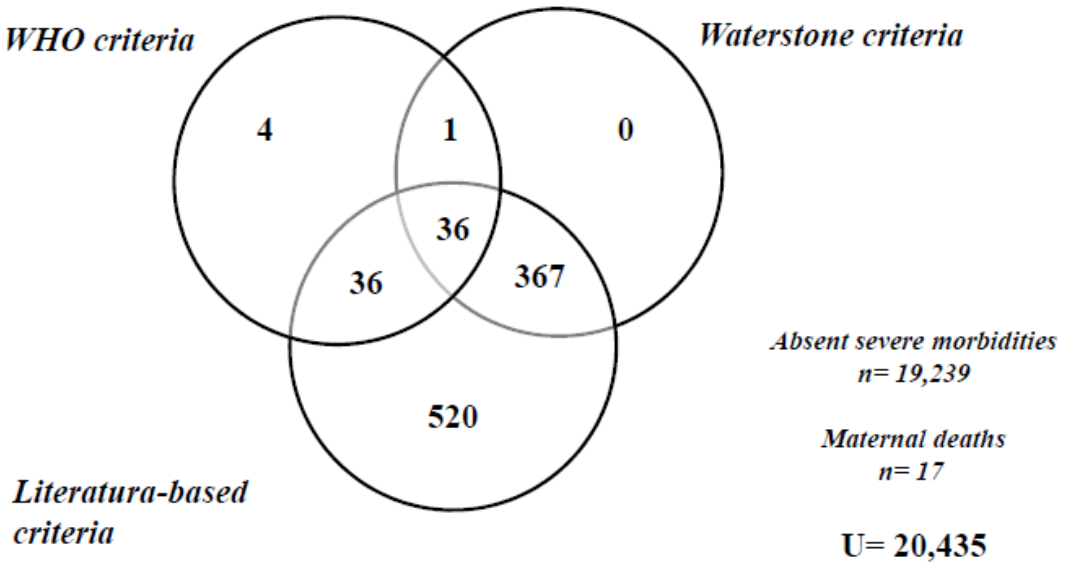

Table 1. Potentially life-threatening conditions

Haemorrhagic disorders
Abruptio placentae
Accreta/increta/percreta placenta
Ectopic pregnancy
Postpartum Haemorrhage
Ruptured uterus
Other systemic disorders
Endometritis
Pulmonary edema
Respiratory failure
Seizures
Sepsis
Shock
Thrombocitopenia <100.000
Thyroid crisis
Hypertensive disorders
Severe pre-eclampsia
Eclampsia
Severe hypertension
Hypertensive encephalopathy
HELLP syndrome
Severe Management Indicators
Blood transfusion

Central venous access

Hysterectomy

ICU admission

Prolonged hospital stay (>7 postpartum days)

Non anaesthetic Intubation

Return to operating room

Surgical intervention

Table 2: The WHO, Waterstone and Literature-based maternal near miss criteria

WHO criteria[a]	Literature-based criteria[b]	Waterstone criteria[c]
Clinical criteria	Severe hypertension	Severe preeclampsia
Acute cyanosis	Eclampsia	Eclampsia
Gasping	Cardiac arrest	HELLP syndrome
Respiratory rate >40 or <6/min	Pulmonary edema	Severe bleeding
Shock	Obstetrical haemorrhage	Severe sepsis
Oliguria non responsive to fluids or diuretics	Uterine rupture	Ruptured uterus
Clotting failure	Admission to intensive care unit	
Loss of consciousness lasting ≥12 hours	Emergent hysterectomy	
Loss of consciousness AND absence of pulse/heart beat	Blood transfusion	

Stroke	Anesthetic accidents or complications
Uncontrollable fit/total paralysis	Urea > 15 mmol/l or creatinine > 400 mmol/l
Jaundice in the presence of pre-eclampsia	Oliguria (<400 ml/24 h)
Laboratory-based criteria	Coma
Oxygen saturation <90% for ≥ 60 minutes	
pH < 7.1	
PaO2/FiO2 < 200 mmHg	
Lactate > 5	
Creatinine ≥ 300 μmol/l or ≥ 3,5 mg/dl	
Acute thrombocytopenia (< 50,000 platelets)	
Bilirubin >100 μmol/l or > 6,0 mg/dl	
Loss of consciousness AND the presence of glucose and ketoacids in urine	
Management-based criteria	
Use of continuous vasoactive drugs	

Intubation and ventilation for ≥ 60 minutes not related to anaesthesia	
Hysterectomy following infection or haemorrhage	
Dialysis for acute renal failure	
Transfusion of ≥ 5 units red cell transfusion	
Cardio-pulmonary resuscitation (CPR)	

[a] Say et al, 2009 [b] Reichenheim et al, 2009 [c] Waterstone et al, 2001

Table 3: Diagnostic properties of Waterstone and literature-based approaches for maternal near miss.[a, b]

	Waterstone % (CI95%)	Literature-based % (CI95%)
Sensitivity	48.05 (36.52-59.74)	93.51 (85.49-97.86)
Specificity	97.73 (97.49-97.95)	94.5 (94.15-94.86)
Positive predictive value	9.16 (6.53-12.40)	7.51 (5.92-9.36)
Negative predictive value	99.75 (99.66-99.82)	99.97 (99.92-99.99)

[a] WHO MNM diagnostic approach was used as a standard reference.

[b] In brackets: CI95%: Confidence Interval 95%.