Risk assessment in Ginecology and Obstetrics in Sicily: an approach based on Wolff's Criteria

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Abstract

Objectives: *To apply Wolff's Criteria to hospital discharge records (HDR) in order to detect adverse events worthy of further study.*

Methods: *Gynecology and Obstetrics Units of three Sicilian hospitals were considered and HDR regarding ordinary and day hospital admissions in 2008 were collected. A matched case-control study was designed, by random selection of 10 controls at maximum for each case. Matching was performed on the variables age and speciality of admission (gynecology or obstetrics).*

Results: *Out of a total of 7011 HDR examined, 114 cases were identified with Wolff's Criteria. Multivariate analysis confirmed a statistically significant association with the origin of admission, diagnosis at the acceptance and length of stay: there was a decreased risk of Wolff's event in patients having urgent admission compared to elective (OR = 0.47, 95% CI = [0.28-0.78]), an increased risk in patients reporting tumor (OR = 5:41, 95 % CI [1.89-15.47]) and other causes (OR = 2.16, 95% CI [1.10-4.24]) compared to delivery diagnosis at acceptance and in patients whose length of stay was more than 6 days (OR = 23.17, 95% CI = [12.56-42.7]) compared to less or equal than 3 days*

Conclusion: *Wolff's Criteria can be applied for the analysis of clinical risk in hospitals with different structural characteristics, on condition that the HDR database is complete and good quality.*

Introduction

The objective of this work was to apply Wolff's Criteria to perform the clinical risk assessment in Gynecology and Obstetrics Units of three Sicilian hospitals, using the hospital discharge records (HDR) database. The study was aimed to calculate the hospital-based prevalence of cases reporting Wolff's Criteria and to evaluate the association with patient specific risk factors.

As several international studies have outlined (1-3), the reason to use Wolff's Criteria in Obstetrics and Gynecology units is the occurrence of many adverse events. Data from the Integrated Process Protection Health of the Court of Human Rights of the patient relative to 2009 (2) showed that complaints concerning ob-

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stetrical and gynecological interventions are the most frequent for the majority of the Italian hospitals. Moreover, some adverse events (maternal death, severe disease related to delivery and childbirth mortality in healthy infant weighing more than 2500 gramms within 48 hours of birth) were also included in the list of sentinel events indicated by the Department of Health and monitored at national level (4).

Materials and Methods

Clinical Risk Management aims to prevent avoidable errors in Health care, to ensure patient safety and ultimately the overall improvement of quality of care (5). We define quality as the absence or decrease in the percentage of errors that can cause undesirable adverse events (5) that result in injury to the patient due to her medical condition, but related to the care process (6).

There are several methods and tools to perform error analysis and risk management that have been developed in recent decades at the international level and also introduced in many parts of the Italian health system (5).

Wolff's Criteria (7), used for many years at the Wimmera Base Hospital in Australia in programs aimed to identify clinical risk, is characterized by the application of the so-called "limited screening", consisting of selection of clinical folders, examination and search of eight indicators, whose presence require further analytical inspection of the clinical documentation.

The criteria proposed by Wolff are: Delisting of the operating room (W1), length of stay exceeding 21 days (W2), transfer to another acute care unit (W3), Cardiac Arrest (W4), Unplanned Readmission within 21 days after discharge (currently equal to 28 days) (W5), transfer from a general care unit to an intensive care unit (W6), Back in the operating room within 7 days (W7), Death (W8).

We considered Operational Unit of Gynecology and Obstetrics of the Hospital S. Antonio Abate of Trapani (TP), the Academic Hospital Policlinico "Paolo Giaccone" of Palermo (AOUP) and the Hospital "Buccheri La Ferla-Fatebenefratelli" of Palermo (FBF). We used the information flow of HDR concerning both ordinary and Day Hospital admissions in 2008 (8). In order to assess statistical significance of patient specific risk factors for the probability to be a Wolff's case, all cases of patients who reported one or more Wolff's Criteria in 2008 were extracted from Information Systems of the three hospitals. A matched case-control study was designed, by random selection of 10 controls at maximum for each case. Matching was performed on the variables age (divided into two classes based on a cutoff of 30 years) and speciality of admission (Gynecology or Obstetrics). The lists of admissions made in 2008 in Obstetrics and Gynecology units of the three hospitals were used as sampling frames and a systematic sampling was performed, calculating the sampling interval as the ratio between the number of admissions and the total number of controls needed for the study. If all the necessary controls to match each case were not obtained from the first sample, it was proceeded to repeat the sampling with the same way, but using an initial seed different from above, until they were 10 controls matched to every case.

The following patient specific risk factors were considered: origin of admission, classified as elective, urgent and transfer from another hospital; diagnosis at the acceptance, classified as tumour, delivery and other causes; systemic comorbidities; specific concomitant diseases of the

genital system; surgical intervention occurrence and length of stay. In the sample there were the following systemic comorbidities: anaemia, hypertension, diabetes mellitus, gestational and other nature, epigastralgia, hypertransaminasemia, renal colic. As concomitant diseases of the genital tract we considered conditions that could have a significant influence on the prognosis and the entire therapeutic process put in place during hospitalization. Some examples are the breech of the foetus, the foetus-pelvic discordance, intrauterine growth retardation, the ectopic pregnancy, the birth of twins, oligohydramnios, placenta previa and previous caesarean delivery: the latter condition requires the subsequent deliveries are always completed by caesarean section, entailing the need for the patient to undergo surgery.

Since HDR were used as an information source for Wolff's Criteria, we proceeded to the "translation" of these events, to apply the information flow of the HDR based on the following encoding schemes:

• W1: We have considered the HDR with primary or secondary diagnosis "use of health services for specific interventions not performed" (code V64);

• W2: It was found by setting the appropriate query for the examination of the database of the hospital that would allow the correct selection of the HDR of interest.

• W3: Admissions in the ordinary rule characterized by transfer to an intensive care unit (ICU), identified by codes of discipline 49 (ICU) and 50 (coronary care unit).

• W4: All discharges with diagnosis of cardiac arrest (code 427.5 in ICD-IX-CM).

• W5: The pairs of repeated admissions that occurred at the same time in the same Unit and for the same MDC admission index, in order to exclude cases of re-admissions for other causes.

• W6: It was detected from the field 27 of HDR, allocated to the mode of discharge.

• W7: The selection of all the cases reporting surgical interventions within seven days period would involve cases whose second intervention could correspond to a planned intervention; to exclude these cases, we proceeded with 1) the analysis of HDR reporting 2 surgical procedures performed in a shorter than seven days period and 2) the analysis of HDR on two different admissions of the same patient, reporting two surgical procedures performed within that period in order to verify if the second surgery was scheduled after the occurrence of a complication related to the previous surgery.

• W 8: it was detected from field 27 of the HDR, as W6.

The association between the presence/absence of one or more Wolff's Criteria and patient specific risk factors was evaluated through univariate analysis, using the McNemar's test, and through multivariate analysis, using the conditional logistic regression model to calculate odds ratios (OR) and 95%confidence intervals. The following reference categories were considered: *election* for the origin of the admission, *delivery* for diagnosis at the acceptance, ≤3 *days* for the length of stay, *A.O.U.P* for the hospital, *No* for the presence of systemic comorbidities, for the specific concomitant diseases of the genital system and for the surgery. It was considered a cut-off of 5% for statistical significance. Statistical analysis was performed with the software Intercooled STATA v. 11.0.

Results

Of 7011 examined HDR, 3560 (50.8%) were at FBF, 2310 (32.9%) HDR at AOUP

and 1141 (16.3%) HDR at TP. Overall 114 Wolff's cases have been detected, respectively 49 (43.0%) at FBF, 42 (36.8%) at AOUP and 23 (20.2%) at TP (Table 1). Therefore it was estimated a prevalence of 1.3% (95% CI = [0.9, 1.7]) at the FBF, 1.8% (95% CI = [1.3, 12.4]) at the AOUP and 2.0% (95% CI = [1.2, 2.8]) at TP, all statistically significant. The overall prevalence was 1.5% (95% CI = [1.3, 1.9]) and no statistically significant difference was found among the three hospitals (p = 0.16).

At TP, two subjects reported two Wolff's Criteria. A patient had W7 and W6, another patient had both W2 and W6: these latter two Wolff's Criteria were simultaneously found also in one HDR of the A.O.U.P.. Another patient at the A.O.U.P., due to her severe clinical status, faced two admissions exceeding 21 days, at a distance of 2 days, becoming fully part of the W5 criterion. Moreover, the second admission was concluded with "transfer to another acute care institute" (Table 1).

Ten controls were matched with one Wolff's case, consisting of women belonging to the same age group and speciality of admission. Overall, 1159 controls were selected, respectively 505 (43.6%) at the FBF, 424 (36.6%) at the A.O.U.P. and 230 (19.8%) at TP. It should be noted the absence of Wolff's cases aged less than 30 years with gynecologic diagnosis at TP and FBF.

At Univariate analysis, a statistically significant association was found between the occurrence of a Wolff Criterion and all considered variables (p <0.001) except for concomitant diseases. There was an increased prevalence of Wolff's cases in patients with elective compared to urgent admission (12% vs. 3.1% at FBF, 10.1% vs. 7.1% at TP and 9.3% vs. 8.8% at A.O.U.P.), in subjects with cancer diagnosis at TP (33.3%) and A.O.U.P. (36.0%) and with a diagnosis of other causes at FBF (9.4%), in patients with concomitant diseases of the genital system at FBF (13.8% vs. 6.6%) and TP (18.8% vs. 5.4 %) and patients without such pathologies at A.O.U.P. (9.3% vs 8.3%), in patients who underwent surgery (11.6% vs. 7.1% at FBF, 11.6% vs. 6.1% at TP, 9.1% vs. 9.0% at A.O.U.P.) and, last, in patients with length of stay more than 6 days in all three hospitals (over 30%) (Table 2). Multivariate analysis confirmed a statistically significant association with origin of

Table 1 - Distribution of Wolff criteria by hospital

Wolff criteria	FBF	TP	A.O.U.P.	Total
W2	43 (87.8)	18 (78.3)	13 (31.0)	74 (64.9)
W3	0 (0)	2 (8.7)	9 (21.4)	11 (9.7)
W4	0 (0)	0 (0)	12 (28.6)	12 (10.5)
W6	6 (12.2)	1 (4.4)	4 (9.5)	11 (9.7)
W7	0 (0)	0 (0)	2 (4.8)	2 (1.8)
W1, W2 and W3	0 (0)	0 (0.0)	1 (2.4)	1 (0.9)
W2 and W3	0 (0)	0 (0.0)	1 (2.4)	1 (0.9)
W2 and W6	0 (0)	1 (4.4)	0 (0)	1 (0.9)
W6 and W7	0 (0)	1 (4.4)	1 (2.4)	1 (0.9)
Total	49 (100.0)	23 (100.0)	42 (100.0)	114 (100.0)

W1 = De-listing of the operating room, W2 = Length of stay exceeds 21 days, W3 = Transfer to another acute care unit, W4 = Cardiac Arrest, W6 = Transfer from a general care unit to an intensive care unit, W7 = Back in the operating room within 7 days.

Table 2 - Occurrence of one or more Wolff criteria with respect to patient specific variables – Univariate Analysis

Variables	FBF				TP				A.O.U.P.			
	N	Wolff cases			N	Wolff cases			N	Wolff cases		
		n	%	p§		n	%	p§		n	%	p§
Origin of admission				<0.001				<0.001				<0.001
Elective	359	43	12.0		178	18	10.1		194	18	9.3	
Urgent	193	6	3.1		70	5	7.1		272	24	8.8	
Diagnosis at the acceptance				<0.001				<0.001				<0.001
Delivery	358	32	8.9		151	17	11.3		240	10	4.2	
Tumour	35	2	5.7		3	1	33.3		259	9	36.0	
Other	159	15	9.4		99	5	5.1		201	23	11.4	
Systemic comorbidities				0.403				0.636				0.030
No	511	39	7.6		226	18	18.0		403	32	7.9	
Yes	41	10	24.4		27	5	18.5		63	10	5.9	
Specific concomitant diseases of the genital system				<0.001				<0.001				<0.001
No	378	25	6.6		184	10	5.4		322	30	9.3	
Yes	174	24	13.8		69	13	18.8		144	12	8.3	
Surgery				<0.001				<0.001				<0.001
No	336	24	7.1		115	7	6.1		201	18	9.0	
Yes	216	25	11.6		138	16	11.6		265	24	9.1	
Length of stay				<0.001				<0.001				<0.001
≤3	249	2	0.8		65	2	3.1		250	14	5.6	
3-|4	97	1	1.0		48	0	0.0		55	2	3.6	
4-|6	82	2	2.4		73	0	0.0		101	2	2.0	
>6	124	44	35.5		253	21	31.3		60	24	40.0	

§McNemar test

the admission, with diagnosis at the acceptance and length of stay. Specifically, there was a decreased risk of Wolff's event in patients with urgent admission (OR = 0.47, 95% CI = [0.28-0.78]), an increased risk in patients with cancer (OR = 5:41, 95 % CI [1.89-15.47]) and other causes (OR = 2.16, 95% CI [1:10 to 4:24]) and in patients hospitalized for more than 6 days (OR = 23.17, 95% CI = [12.56-42.7]) (Table 3).

Discussions

Wolff's Criteria are widely used in clinical risk management (9-11), but there is scarce literature aimed to demonstrate the validity of these criteria. In our study Wolff' s criteria have been found in all examined structures, without any statistically significant difference among them, showing that these criteria can be applied for clinical risk assessment in healthcare

Table 3 - Occurrence of one or more Wolff criteria with respect to patient specific variables – Multivariate Analysis

Variables[c]	OR	95%CI	p	95%CI
Origin of admission				
Urgent vs Elective	0.47	[0.28-0.78]	0.004	[0.28-0.78]
				[1.89-15.47]
Diagnosis at the acceptance				[1.10-4.24]
Tumour vs Delivery	5.41	[1.89-15.47]	0.004	
Other vs Delivery	2.16	[1.10-4.24]	0.026	
Specific concomitant diseases of the genital system				
Yes vs No	1.31	[0.78-2.20]	0.307	
Surgery				
Yes vs No	0.87	[0.54-1.41]	0.576	[0.54-1.41]
Length of stay				
3-|4 vs ≤3	0.60	[0.17-2.11]	0.425	[0.17-2.11]
4-|6 vs ≤3	0.64	[0.21-1.97]	0.432	[0.21-1.97]
>6 vs ≤3	**23.17**	**[12.56-42.7]**	**<0.001**	**[12.56-42.7]**
Hospital				
TP vs A.O.U.P.	0.51	[0.26-1.01]	0.052	[0.26-1.01]
FBF vs A.O.U.P.	0.62	[0.35-1.12]	0.113	[0.35-1.12]

[§] Only significant variables at univariate analysis have been included

organizations with different structural characteristics, as hospitals involved in our study. A.O.U.P. was a national high-skilled hospital, FBF was a profit hospital and TP was a medium-sized hospital of a small town. Moreover, these structures had a different organization of care, as it could be derived from the lack of Wolff's Criteria in the age group under 30 years with gynaecological diagnosis both at TP and at FBF, both hospitals oriented to obstetrics care. Alternatively, Wolff's Criteria were found in patients at AOUP aged less than 30 years old with both obstetric and gynaecological diagnosis, evidence of uniformity in the mission of care.

With regard to patients at TP and AOUP reporting at the same time several Wolff's Criteria, as it could be derived from the analysis of their HDR, the

clinical complexity would be the cause of mismanagement, because of the substantial commitment of resources required by complex cases.

The statistically significant occurrence of Wolff's Criteria in patients with elective compared to urgent admission, that was derived from both univariate and multivariate analyses, confirmed the evidence from the international literature that errors in elective admission are more frequent than in urgent admission, because of organizational and communication drawbacks that arise among health care professionals in elective care (12).

Finally, the relationship between the occurrence of Wolff's Criteria and the surgery seems to be confused by the strong association between surgery and length of stay. The highest statistically significant association with length of stay

more than six days can be explained by the highest prevalence of W2 criterion in the sample.

In general, from the database of the HDR, indicators of potentially adverse events are easily available and have the advantage of high applicability. However, the limitations of the database and caution in the accurate reading and interpretation of produced information have to be considered: HDR database must show completeness of coding and data quality, especially in order to compare different health facilities. For this reason it is necessary to involve physicians in the selection of the HDR for further investigation, since they have the necessary skills to identify coding errors and inaccuracies and also to distinguish the presence of adverse events from situations that could occur in the management of complex clinical cases and not dependent on health care malpractice.

The review of medical records is a multidisciplinary approach that allows the healthcare professionals to increase the awareness of health-care risk, sharing formal and substantive requirements of the medical record, which could lead to change in the agents' behaviour, especially if the hospitals are implementing educational interventions, as a key element for clinical risk management. It should be remembered that the analysis of medical records is a tool used in the phase of identification of risk, but must be combined with other tools to the management of clinical risk, such as root cause analysis or the clinical audit. They are procedures aimed to improve the supply of care through the retrospective analysis and systematic comparison of the provided benefits trough explicit criteria, the implementation of changes at individual and team levels, and the subsequent monitoring of the introduced correction factors (13).

Riassunto

La valutazione del rischio clinico in ginecologia e ostetricia in Sicilia: un approccio basato sugli indicatori di Wolff

Obiettivi: Applicare i Criteri di Wolff alle Schede di Dimissione Ospedaliera (SDO) per individuare eventi avversi che necessitano di ulteriore approfondimento

Metodi: Sono state considerate le SDO dei ricoveri ordinari e in Day Hospital delle Unità Operative di Ginecologia e Ostetricia di tre ospedali siciliani, relativamente al 2008. È stato utilizzato uno studio caso-controllo appaiato, con l'estrazione casuale di 10 controlli per ciascun caso. L'appaiamento è stato effettuato sulle variabili età e specialità (Ginecologia o Ostetricia).

Risultati: Su un totale di 7011 SDO esaminate, sono stati individuati 114 casi con Criteri di Wolff. L'analisi multivariata ha confermato l'associazione statisticamente significativa con l'origine del ricovero, la diagnosi all'accettazione e la durata della degenza. In particolare, si è stimato un minor rischio di Criterio di Wolff in pazienti con ricovero in urgenza rispetto al ricovero in elezione (OR = 0.47, 95% CI = [0.28-0.78]), un rischio maggiore in pazienti con tumore (OR = 5:41, 95 % CI [1.89-15.47]) e altra diagnosi (OR = 2.16, 95% CI [1.10-4.24]) in confronto al parto e in pazienti con durata della degenza superiore a 6 giorni (OR = 23.17, 95% CI = [12.56-42.7]) rispetto alla durata minore o uguale a 3 giorni.

Conclusione: I Criteri di Wolff possono essere applicati per l'analisi del rischio clinico in ospedali con caratteristiche strutturali diverse a condizione che il database delle SDO sia completo e di buona qualità.

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