



Original article

Incidence of adverse events in a general surgery unit

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Objective: Clinical practice is an activity accompanied by risks and uncertainties. The objectives are: to determine the incidence of patients with adverse events (AE) in a general surgery unit; to analyse the associated factors; to consider their impact and to identify the prevention possibilities.

Patients and method: Ambispective study in patients taken care of in a general surgery unit in a tertiary hospital. Every admission was prospectively reviewed using a screening guide, with all the clinical histories that fulfilled screening criteria being examined retrospectively using a modular questionnaire.

Results: A total of 989 histories were reviewed, the positive predictive value (PPV) of the screening guide for AE was 53%. The accumulated incidence of patients with AE was 17.8% and the incidence density of AE was 1.92 for every 100 days of hospitalisation. Intrinsic and extrinsic risk factors were associated to greater risk of EA, the most frequent events being: nosocomial infections (54.4%), surgical problems (31.8%), and problems associated with medication (7.4%). A total of 66.8% of the AE were considered moderate, with 53.5% of all AE being preventable.

Conclusions: The screening questionnaire was useful for the valuation of adverse events. AE are common in surgical patients which has an effect on the use of other hospital resources. The most important associated factors were: length of stay, surgical and extrinsic factors and surgical wound infection as the main AE. Two thirds of AE were considered moderate and half of all AE were considered avoidable.

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Incidencia de efectos adversos en un servicio de cirugía general

R E S U M E N

Palabras clave:
Efectos adversos
Seguridad del paciente
Calidad asistenciales

Objetivo: La práctica clínica es una actividad acompañada de riesgos e incertidumbre. Los objetivos son estimar la incidencia de pacientes quirúrgicos con efectos adversos (EA), analizar los factores asociados y estimar su impacto e identificar las posibilidades de prevención.

Pacientes y método: Estudio ambispectivo de los pacientes atendidos en una unidad de un servicio de cirugía general de un hospital de tercer nivel. La revisión de todos los ingresos se realizó de forma prospectiva con una guía de cribado, examinándose de manera retrospectiva con un cuestionario modular todas las historias clínicas que cumplieron criterios de cribado.

Resultados: Se revisaron 989 historias con un valor predictivo positivo (VPP) para EA de la guía de cribado de 53%. La incidencia acumulada de pacientes con EA fue del 17,8% y la densidad de incidencia de EA de 1,92/100 días de hospitalización. Los factores intrínsecos y extrínsecos se asociaron a mayor riesgo de EA; los eventos más frecuentes fueron las infecciones nosocomiales (54,4%) y los problemas quirúrgicos (31,8%) y los de medicación (7,4%). El 66,8% de los EA fueron considerados moderados (el 53,5% de todos los EA evitables).

Conclusiones: El cuestionario de cribado ha sido útil para la valoración de EA. Los EA son frecuentes en pacientes quirúrgicos y repercuten en la utilización de los recursos hospitalarios. Los factores asociados más relevantes fueron la estancia, la intervención quirúrgica y los factores extrínsecos. De los EA, destacó la infección de herida quirúrgica. Por su impacto, dos tercios fueron moderados y se consideró evitables la mitad de todos los EA.

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Introduction

The growing complexity of health systems may favour the increase of adverse events (AE), making it necessary to know their frequency and distribution. Various studies have revealed their impact in morbidity and mortality,¹ but in our environment, there are few prospective studies on AE in surgical units.

The elements that define² an AE are: non-intentioned physical disorder not caused from the evolution of the disease, that is seen as damaging, and it is originated in the health care provided.

The Harvard Medical Practice Study³ is considered to be the reference in research on AE. The incidence was estimated at 3.7%. With a similar methodology, the Utah and Colorado study⁴ was done, founding an incidence of 2.9%, and afterwards, the Quality Australian Health Care Study⁵ with a rate of 16.6%. Others carried out in the United Kingdom,⁶ Australia,⁷ Canada,^{8,9} Denmark,¹⁰ and New Zealand¹¹ demonstrated the magnitude of the problem when estimating that 7.5% to 12.7% of hospitalised patients suffered an adverse event.

Among the prospective studies, the following 2 stand out, Andrews et al¹² with 45.8% of AE, and Healey et al,¹³ with 31.5%.

In Spain, the IDEA¹⁴ (*Identificación de Efectos Adversos-Identificación of Adverse Events*) research project was carried out, observing an incidence rate of 9.3%. On the basis of this study, the National Study of Adverse Events (ENEAS –*Estudio Nacional de Efectos Adversos*) was developed in 2005, obtaining an incidence in general surgery units¹⁶ of 10.5%.

The retrospective study by Aguiló et al¹⁷ also stands out with 16.3% of post-surgical complications.

The goals of this study are to evaluate the usefulness of a screening guide for AE and complications, to estimate the incidence of AE in a general surgery unit, to analyse the variables that increase the risk of AE and to estimate the impact and the possibilities for prevention.

Patients and method

Ambi-spective study of all patients older than 14 years hospitalised more than 24 h in a general surgery unit of a third level hospital, from February 2004 to February 2005, that finished when all of the patients had been discharged.

Exclusion criteria included the following: admitted to hospital before the beginning of the study, admitted to the unit but belonging to other departments, and patients of the unit that were admitted in other nursing units.

The principle sources of information were the clinical records, and the evaluation was done in 2 phases:

- Prospective follow-up during hospitalisation: the researcher went to the nursing unit of the corresponding service every 2 days to review all of the clinical records of the hospitalised patients with a screening guide (Table 1) to detect possible AEs and to identify patient variables and 19 alerting items for potential AE.
- Retrospective revision of patients positive for one or more of the screening items. For this, the discharge form

and clinical records of the patient were reviewed with a surgeon from the unit, using a 5 module form (MRF2¹⁵: modular review form of possible AE): identify AE (module A); describe the lesion and the effects (B); moment of appearance (C); principal problems (D); and prevention possibilities (E).

Finally, the CIE-9 diagnosis (to calculate the Charlson¹⁸ index) and procedure codes were solicited from the

documentation department along with the GRD and number of admissions (in order to know the losses of the study).

The specific definitions used were those from the ENEAS study¹⁵ (Figure 1). Bearing in mind the impact, AEs were considered as mild (they did not extend hospital stay), moderate (they extended hospital stay by at least 1 day), and severe (death, residual invalidity, or additional surgical intervention) and those events where the surgeon estimated a prevention probability from moderate to complete, in a Likert

Table 1 – Variables collected in the screening guide

Age	
Sex	
Stay	
Intrinsic factors	Coma, renal insufficiency, diabetes mellitus, neoplasia, immunodeficiency, chronic pulmonary disease, neutropenia, liver cyrrhosis, drug addiction. obesity, hypoalbuminemia, pressure ulcer, deformities, cardiac insufficiency, coronary disease, and hypertension
Extrinsic factors	Urinary catheter, peripheral and central venous catheters, arterial catheter, peripherally-inserted central catheter, venous, arterial or umbilical catheter, parenteral nutrition, enteral nutrition, naso-gastric tube, tracheostomy, mechanical ventilation, and immune-suppressive treatment
Alert items	Previous hospitalisation in the last year; previous anti-neoplastic treatment; traumatism; adverse medication reaction; fever >38.3°C the day before discharge; transfer to the special care unit; transfer to another acute patient hospital; second surgical intervention; organ lesions; new neurological deficit; acute myocardial infarction; acute stroke or pulmonary thromboembolism after a procedure; heart attack; birth, death, unforeseen surgical intervention; complication of ambulatory surgery; some other adverse event; suggestive notes of lawsuit; nosocomial infection

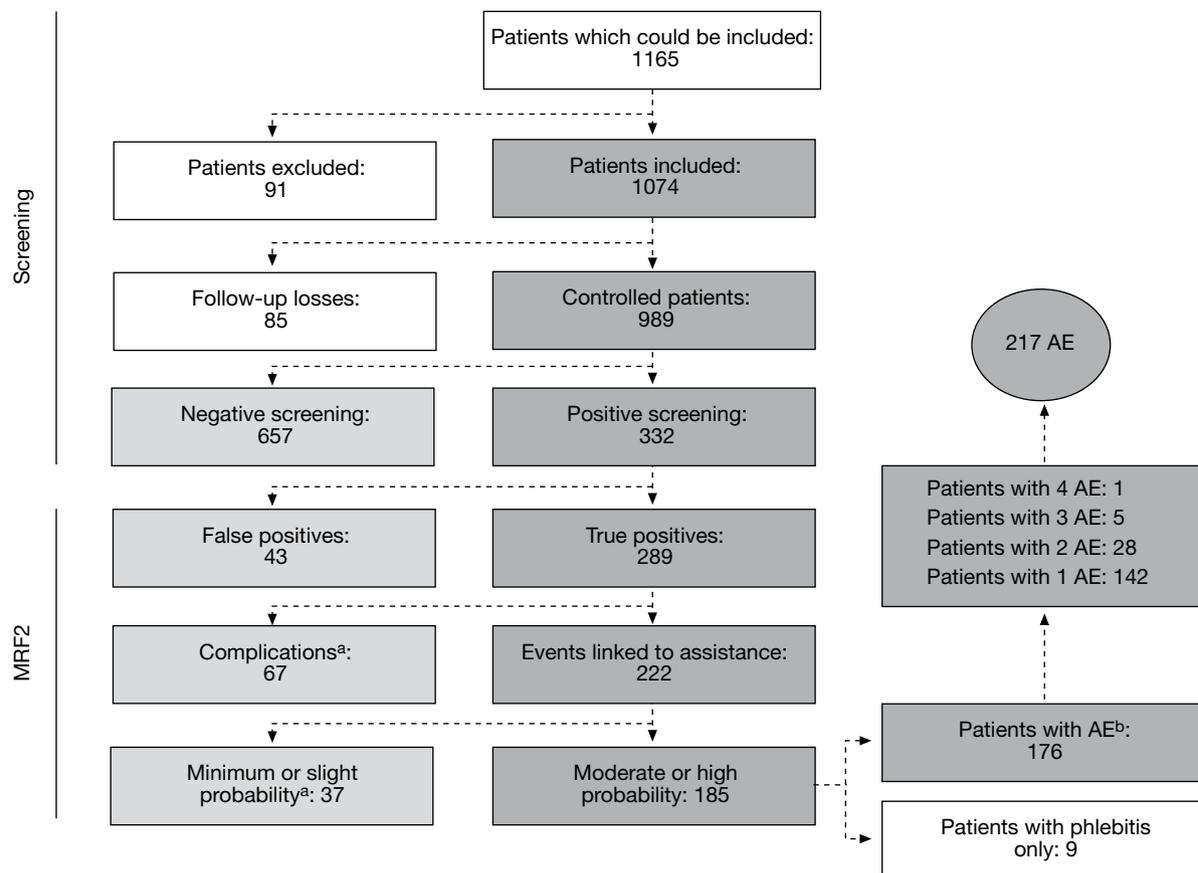


Figure 1 – Principal results in patients. AE indicates adverse events.

^aComplications (67+37=114): patients with normal complications—decompensation from the base disease of the patient—and patients with events of minimal to slight probability to be related with health care assistance.

^bOnly patients with events with moderate to high probability of having been produced by the health care assistance provided. Phlebitis is excluded.

scale of 6 categories from absence to complete possibility of prevention, were considered avoidable. The extension of hospital stay was evaluated by the surgeon, considering the type of AE, treatment, disease, and co-morbidity. The complexity of the patient was evaluated using the average weight by GRD and the presence of risk factors. The predictive value of the screening guide was evaluated (for complications and AE together, as well as for only AEs) using the MRF2¹⁵ as a standard. The sample was described using the mean (standard deviation) for continuous variables and frequencies for the categorical ones. The χ^2 was used to associate qualitative variables and the Student t test, or the Mann-Whitney U test for quantitative variables, according to normality criteria. Accumulated incidences, incidence densities, and relative risks were obtained. Finally, a multi-variable analysis of logistic regression was carried out selecting co-variables for their bibliographic relevance and the previous bivariable analysis. The contrasts were bilateral, with a significance level of $P < .05$ and 95% confidence intervals (CI). The statistical analyses were carried out using the SPSS program, version 15.

Results

Nine hundred eighty-nine admissions were evaluated (41% were emergencies) of 891 patients (Figure 1). The average age was 58.1 (18) years, 52.8% were women and the average

stay was 11.4 (12) days, accumulating a total of 11 264 stays. Average weight was 2.04 (2.3); for patients that had been operated on, 2.14 (2.3) and that of patients that had not been operated on, 1.37 (2.3) ($P < .001$); 332 (33.6%) of the admitted patients presented one or more of the 19 items, the most frequent were: nosocomial infection (16.5%), previous hospitalisation in the last year (12.4%), some other AE (8.2%) and second surgical intervention during their admission (4.4%).

The PPV of the screening guide for complications as well as for AEs was 87% (289/332; 95% CI, 83–90.5) and for patients with only AE, 53% (176/332; 95% CI, 47.5–58.5) (Figure 1).

The accumulated incidence of patients with AE was 17.8% (95% CI, 15.5–20.3). Of the 176 patients with AEs, in 42 (23.9%), it started before the studied hospital stay, causing the accumulated incidence in the hospital period studied to be 13.5% (95% CI, 11.5–15.8).

The number of AEs per patient was 1.2; in the period of hospitalisation studied, 175 AEs were produced in 10 738 stays, with an incidence density of AEs of 1.63/100 (1.40–1.90/100) days and for moderate or severe AEs, 13.6/1000 (11.5–16/1000) days.

The average age of the patients with AEs was 64 (16) years old, while the average age of those that did not present AEs was 56 (18) ($P < .001$). The patients with AEs remained hospitalised for an average of 25.1 (15) days, while those without them stayed 9.1 (11) days ($P < .001$), causing an average increase of 7.9 stays per patient with AEs.

Table 2 – Accumulated incidence, relative risk, and statistical significance

Factor	AI ^a	RR	p ^b
Age			
<65 years	14.2 (11.4–17.3)		
≥65 years old	22.9 (18.9–27.3)	1.62 (1.24–2.12)	<.001
Sex			
Males	20.3 (16.8–24.3)	1.31 (1–1.72)	.048
Females	15.5 (12.5–18.9)		
Admission ^c			
Emergency	14 (10.6–17.9)		
Programmed	14.4 (11.6–17.5)	1.03 (0.75–1.42)	.861
Surgery ^c			
Yes	15 (12.7–17.6)	2.1 (1.01–4.38)	.034
No	7.1 (2.9–14.2)		
Stay ^c			
<1 week	26.1 (24.1–32.6)	17.4 (8.6–35.2)	<.001
>1 week	1.6 (0.7–3.2)		
Intrinsic factors			
Yes	22.8 (19.7–26.2)	2.84 (1.93–4.19)	<.001
No	8 (5.3–11.5)		
Extrinsic factors ^c			
Yes	28.1 (23.8–32.8)	7.56 (4.78–11.94)	<.001
No	3.7 (2.3–6)		
Charlson index ¹⁸			
0	15.5 (12.9–18.4)		
1–10	23.4 (18.6–28.7)	1.51 (1.15–1.98)	.003

RR indicates relative risk.

^aAccumulated incidence with its confidence interval of 95% for each factor; accumulated incidence in 1 year multiplied by 100.

^b χ^2 .

^cIn these variables, the patients with adverse events before admission were not considered.

The average weight of the patients with AE was 3.57 (3.2) and of those that did not suffer them, 1.71 (1.9) ($P<.001$). Regarding sex, the average weight in males was 2.15 (2.4) and in women, 1.94 (2.1), without significant differences, that were present ($P<.001$) for age, 2.45 (2.5) for those 65 or older and 1.75 (2) in those younger than 65 years old.

The principal risk factors and their possible association with AEs are presented in Table 2, and a dose-response effect is shown regarding said risk factors ($P<.001$). The multivariable logistic regression model is shown in Table 3.

The distribution of the AEs according to the moment when they occurred and of what type is presented in Table 4.

Regarding the repercussion of the AE on hospital stay, it was found that 27 (12.4%) did not cause an increase, 148 (68.2%) increased a part of the stay, and 42 (19.4%) needed to be re-admitted.

Fifty-three point five percent of the AE were considered to be preventable, without evidence of associations between the prevention possibilities and their severity. The average additional stays per patient were 9.7, of which 5.6 could be considered as avoidable.

Discussion

The study of the AE in general surgery units has taken on a special relevance.^{3-6,8} The incidence of AE could have been underestimated by not including those identified after discharges, although the previous admissions were analysed as possible AEs, AEs that did not cause readmissions (AEs that did not require attention, AEs attended to in primary care or the emergency unit); the patients admitted in this unit that

did not belong to the department, as well as those AEs that occurred outside of the hospitalisation of the unit evaluated were not included.

The screening guide has been used in the principle studies carried out, with high sensitivity (84%). The PPV calculated from the MRF²¹⁵ was 87% for patients with complications and AEs and 53% for patients with only AEs, rates that are higher than those obtained in other studies: 16.3%,³ 16.9%,⁸ 20.5%,⁹ 20.8%,⁴ and 38%.⁵

Thirty-three point two percent of the patients presented one or more of the 19 criteria of the screening guide, similar to that found in other studies.^{3,5,8,15}

The accumulated incidence of patients with AEs from hospital assistance was 17.8%, greater than that from the ENEAS study¹⁵ (9.3%) and those of the classic studies^{3,4,6,8-11,19} (Figure 2). It must be pointed out that these studies were carried out with retrospective methodology, in medical and surgical departments and patients with low risk were not usually excluded.

In the ENEAS study,¹⁵ the incidence in surgical patients was 8.1%, lower than that for medical units (8.9%), while in the general surgery units of hospitals with more than 500 beds, it was 12.5% (95% CI, 8.2-16.8),¹⁶ slightly lower than that obtained in our study. When comparing the results with 2 studies on surgical patients, also done with prospective methodology, similar incidences were observed (17.8% and 19.9%). In addition, in a study carried out within the IDEA project,²⁰ the incidence of AEs in the general surgery unit was estimated to be 16.1%.

In 23.9% of the patients, the AE started before the admission studied, a rate slightly inferior to those reported by other studies (25.7%¹⁵ and 31%⁸), and 15.7% of the analysed AEs caused re-admission, of which the most frequent were from post-surgical abscesses and infection of the surgical wound, corresponding with those found in the ENEAS study¹⁵ except regarding medication problems. The readmissions were studied meticulously in the study by Martínez et al,²¹ founding that 20.9% were related with health care quality.

The average age of the patients included was greater than that from other studies (44.85 and 46.5 years)¹²; the age of the patients with AE was 7 years older, with a relative risk of AE in those older than 65 years of 1.62. This fact is comparable to those from the ENEAS study, where the average age of the subjects with AE was 12 years old, with a relative risk of 2.

The possibility of differences in variables of risk was evaluated and it was observed that there were no differences in age and weight of the GRD, but there was in hospital stay (greater in males).

There were no significant differences regarding the type of admission. In studies such as the one from Aguiló et al¹⁷ and Forster et al,⁹ they observed more complications in the emergency admissions than in the programmed admissions.

In the multivariable model, the statistically significant variables associated to a greater risk of AEs were the presence of extrinsic risk factors, having been operated on during the stay, stay >1 week and the interaction between age and the presence of intrinsic factors. This data does not coincide with the logistical regression of the ENEAS study,¹⁵ as the AEs and the variables introduced were not the same ones.

Table 3 – Logistical regression. Explanatory model

	OR (95% CI)	P
Age ^a	0.350 ^b (0.092–1.333)	.124
Presence of intrinsic factors ^c	0.942 ^a (0.470–1.886)	.886
Presence of extrinsic factors ^d	2.481 (1,381–4,455)	.002
Surgery ^e	0.343 (0.150–0.783)	.011
Stay ^f	13.244 (5.839–30.038)	<.001
Interaction ^g	4.221 (1.031–17.28)	.045
Constant	.014	

CI indicates confidence interval; OR, odds ratio.

^aUp to 65 years compared to those older than 65 years. Reference category: under 65 years old.

^bNot significant.

^cReference category: absence of intrinsic risk factors.

^dReference category: absence of extrinsic risk factors.

^eReference category: operation carried out during studied admission.

^fLess than or greater than 1 week. Reference category: <1 week.

^gThose patients under 65 years of age that presented intrinsic risk factors had less risk of suffering adverse events (OR=0.942), although it was not significant; those over 65 years of age had less risk (OR=0.350), also not significant, and those older than 65 years of age with intrinsic risk factors had 1.4 times more risk (0.350×0.942×4.221=1.391).

Table 4 – Distribution of the different adverse events that occurred depending on the period when they were produced

Types of AE	No.	% ^a	% ^b
<i>AEs before admission^c</i>	42	100	19.4
Infection of surgical wound	4	9.5	1.8
Post-surgical abscess	9	21.4	4.1
Other type of nosocomial infection or nosocomial infection without specification	1	2.4	0.5
Dehiscence of sutures	3	7.1	1.4
Ineffective or incomplete surgical intervention	3	7.1	1.4
Adherences and functional alterations after the surgical intervention	3	7.1	1.4
Other complications after the surgical intervention or procedure	10	23.8	4.6
Bleeding or bruising related with the surgical intervention	1	2.4	0.5
Suspension of surgery	8	19	3.7
<i>AE at the moment of admission</i>	2	100	0.9
Suspension of surgery	2	100	0.9
<i>AE during procedure from principal problem</i>	101	100	46.5
Infection of surgical wound	44	43.6	20.3
Post-surgical abscess	8	7.9	3.7
Dehiscence of sutures	18	17.8	8.3
Ineffective or incomplete surgical intervention	2	2	0.9
Evisceration or evisceration	5	5	2.3
Lesion of an organ during a procedure	3	3	1.4
Adherences and functional alterations after the surgical intervention	3	3	1.4
Other complications after the surgical intervention or procedure	4	4	1.8
Bleeding or bruising related with the surgical intervention	13	12.9	6
Error in the diagnosis	1	1	0.5
<i>AE related with post-operative period or in ICU</i>	7	100	3.2
Bacteraemia related with devices	2	28.6	0.9
Nosocomial infection of the urinary tract	2	28.6	0.9
Nosocomial pneumonia	2	28.6	0.9
Itchiness, erythema or skin lesions reactive to drugs or bandages	1	14.3	0.5
<i>AE related with care provided in hospital ward</i>	65	100	30
Infection of surgical wound	11	16.9	5.1
Bacteraemia related with devices	17	26.2	7.8
Nosocomial infection of the urinary tract	11	16.9	5.1
Nosocomial pneumonia	7	10.8	3.2
Itchiness, erythema or skin lesions reactive to drugs or bandages	5	7.7	2.3
Nausea, vomiting, or diarrhoea secondary to medication	3	4.6	1.4
Hypotension from drugs	1	1.5	0.5
Headache from drugs	1	1.5	0.5
Other secondary effects from drugs	2	3.1	0.9
Opportunist infection from immunosuppressive treatment	1	1.5	0.5
Neurological alterations from drugs	2	3.1	0.9
Bleeding or bruising related with the surgical intervention	1	1.5	0.5
Suspension of surgery	2	3.1	0.9
Pressure ulcer	1	1.5	0.5
<i>AE from mistake at the moment of discharge</i>	0	0	0
TOTAL	217	100	100

AE indicates adverse events.

^aPercentage of AE compared to the total AEs of each group.

^bPercentage of AE compared with the total AEs.

^cAll caused readmission except for the suspension of surgery.

The avoidable AE rate was 53.5%, slightly higher than those from other studies^{3-6,9,10,15} (between 27.6% and 51.2%), without any relationship between the prevention possibilities and the severity of the effect.

The most frequent AEs were nosocomial infections (54.4%), from the procedure (31.8%) and from medication (7.4%), coinciding with the ENEAS in the general surgery units¹⁶ (41.7%, 27.1%, and 24%, respectively). Individually, the most

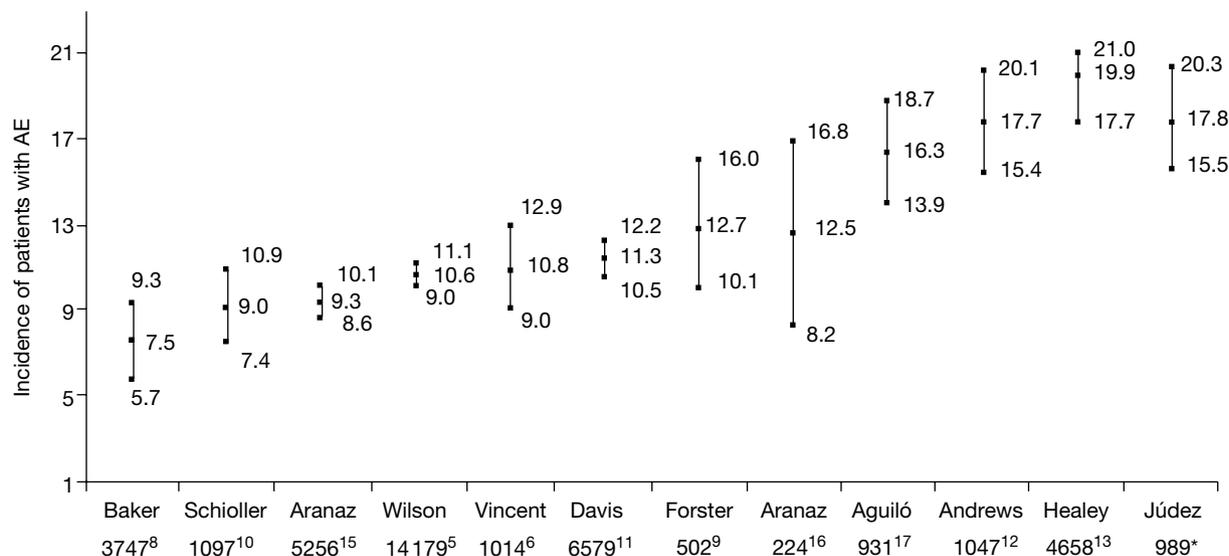


Figure 2 – Incidence of patients with adverse events in the principle studies.

frequent AEs were infected surgery wounds, dehiscences of sutures, and bacteraemias related with devices, results that coincide with these studies.

The comparisons between the studies that analyse the incidence of AEs should be done with caution because of the inexistence of a common AE taxonomy,²² different methodologies, target population, and different timeframes, as well as value judgements. In any case, the knowledge of the AEs makes it possible to supervise their values, compare them with standards and to establish prevention strategies.

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