Right to privacy and informed consent. The authors declare that no patient data appears in this article.

Reference

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Reply to: Risk factors for infection in total knee arthroplasty, including previously unreported intraoperative fracture and deep venous thrombosis☆

Réplica a: Factores de riesgo para la infección en prótesis de rodilla, incluyendo la fractura intraoperatoria y la trombosis venosa profunda, no descritos previamente

Dear Editor,

We share the interest of Dr. Arriaza and Dr. Saavedra in understanding the risk of infection in knee arthroplasty, and we will try to answer the statistical questions they have asked about the paper.

The paper does indeed state that intraoperative fracture is a risk with statistical significance per se, even though only one case of this occurred. We did not forget at any time that this was a single case, and even in the original paper we warned and explained at all times that as it was a single case it had to be considered with the appropriate precaution, and that statistical significance is based on a unique event in a series of cases of infection. Once again in the discussion we stated that ''we know of no previous description of an intraoperative fracture as a risk factor for knee arthroplasty, and in our comparison it was significantly more frequent among infected patients, although it has to be said that statistical significance is attained with a single infected case with no uninfected control''. I.e., we tried to make it absolutely clear that this is a new result which has to be approached with due caution, and that more research is required, although the results indicate that it may be relevant to take intraoperative fractures into account as a risk factor.

As to whether the prolonged duration of surgery associated with an intraoperative fracture could be the risk factor in itself, and not the fracture, we would like to clarify that it no case did this study aim to investigate the interactions between variables (in this case, between the intraoperative fracture and the duration of the surgical operation). As we explained in the methodology, the sample is small, so that it would be too risky (and imprudent) to statistically analyse the interaction of risk factors. Moreover, as you yourselves state, there is a single case of intraoperative fracture, so that seeking a relationship between this fracture and the duration of the operation would be, at the very least, imprudent. This is a very new study which explores many factors simultaneously; the fundamental contribution of the study is based on analysing possible risk factors. Study of the interactions between them will be the object of analysis in subsequent studies that would be impossible to undertake without this previous research.

On the other hand your suggestion that the duration of the surgical operation may be the risk factor in itself, and not the fracture (the specific cause why the operation was prolonged) is erroneous from a methodological and statistical viewpoint. Both events (the fracture and the time) arose at the same time, so that it is impossible to establish a causal relationship with one of them (as they state that time would be the risk factor in itself) while negating the causal relationship with the other one (the fracture).[1] When 2 events occur at the same time it is not possible to establish any type of causal relationship whatsoever for one of them, given that the effect of one cannot be separated from the effect of the other. Both aspects (time and fracture) could perfectly well be independent risk factors for the development of an infection.

Regarding their remark on the validity of the Chi-squared analysis when the value is less than 5 (as is the case with the intraoperative fracture) it has to be pointed out that the criterion for carrying out this statistical analysis is not based on the frequency that is observed, but rather on the frequency that is expected.[2,3] It is true that 50% of the boxes do not fulfil the observed frequency of 5; nevertheless, authors such as Carrasco[4] state that a previous condition for the Chi-squared test is that the theoretical boxes (i.e., the expected frequency, and not the observed frequency, as you state in this reply) contain at least 5 individuals. Our contingency tables therefore fulfil the basic requisite to be able to be interpreted in terms of significance. Additionally, we wish to point out that the relationship of the variables and their clinical relevance has been quantified with the OR. Lastly, as we pointed out, due to the low frequency observed these results have to be analysed cautiously, as we do in the article.

Respecting the doubts that arose for you about the ''low weight'' factor (BMI < 20) and the similarity of results that

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you believe should exist with those of the fracture, as well as the supposition that at least one of the 2 values is incorrect, we would like to clarify that no variable at all is incorrect. Obviously, we understand this remark to be due once again to a lack of statistical comprehension. Any analysis of this type is based on a 2×2 table, which is the one that makes it possible to find Chi-squared, given that there are 2 variables: fracture (yes/no) and group (infection/no infection). The 2×2 table is obtained by crossing these two variables. As is obvious, in Table 2 of our study it makes no sense to show the value of the 4 boxes and only the most relevant information is shown, on the cases with a fracture in both groups. The fact that there is a single case in a Chi-squared box does not imply at all that they will have the same level of significance, given that the result of statistical analysis depends on the distribution of the cases and the expected frequencies in the cross of both variables.[2–4] To make such a simplification and think this is a statistical error.

We agree with you that type of previous surgery performed and its associated factors (anatomical distortion, multiple incisions, osteosynthesis material to be extracted, etc.) is important. Nevertheless, and as was pointed out above, the interactions between the variables studied are not covered by this paper. It is necessary to first carry out a descriptive study of all of the variables before going on to analyse interactions such as the one considered here (previous surgery – duration of the surgical operation). We understand surgery in the past as a risk factor for infection is a datum with intrinsic value, regardless of the type of operation. On the other hand, once again it would be risky to try to draw conclusions based on the type of surgery performed in this relatively small sample, if proceeding with scientific rigour. We wish once again to underline that the fundamental aim of the paper is based on the analysis of risk factors; study of the interactions between them or increased specificity within each one of these factors will be the object of subsequent studies with larger samples, taking this descriptive study as the basis.

We would like to thank the authors for their input and hope to be able to complement these data with ongoing studies of the interactions between the factors analysed here.

Level of evidence

Level of evidence III.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed conform to the ethical norms of the responsible human experimentation committee and the World Medical Association and the Helsinki Declaration.

Confidentiality of data. The authors declare that they followed the protocols of their work centre on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the informed consent of the patients or subjects mentioned in the paper. This document is held by the corresponding author.

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Conflict of interests

The authors have no conflict of interests to declare.

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