The Oslo Balloon Angioplasty versus Conservative Treatment Study (OBACT). The 2-years results of a single centre, prospective, randomised study in patients with intermittent claudication

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Sir,

We would like to complement dr. Nylænde et al.1 for the clear design and the strict follow-up of their study. Unfortunately, the number of patients available for analysis is small. More importantly, the authors have erroneously used the SF-36 as a QoL measure. This instrument has been developed as a measure of health status and the risks of its misuse as a QoL measure have been brought to attention.2 The CLAU-S should also be regarded as a measure of health status rather than QoL. Health status reflects patients’ functioning, whereas QoL also reflects a person’s individual evaluation of functioning.2

The authors estimated “QoL” to improve by 20% after conservative treatment and 40% after PTA. However, they did not explain how they arrived at these percentages and what this would mean for the patient. Since haemodynamic status has a weak relationship with walking ability and walking ability only partially predicts a patient’s QoL,3 the question arises what the clinical relevance of the estimated improvements would be, even if these were statistically significant.

The putative “QoL” results are expressed in unspecified numbers instead of actual scores and are, therefore, difficult to interpret. There were changes in SF-36 scores from baseline results at 3 months, which disappeared at 12 months, but surprisingly, re-appeared for Physical Functioning after 24 months. This suggests an influence from non-studied variables on health status. A similar lack of clarity appears for the CLAU-S scores showing differences for Pain and Every day life. The meaning and interpretation of these differences are not commented.

The authors calculated statistical differences in “QoL” scores using the mean values of the two groups, which illustrate a misunderstanding of the concept of QoL. QoL is highly individual and summing scores from more than one person eliminates individual values. The use of paired t-tests, to compare pre- and post-intervention scores within each participant would have been more in agreement with the concept of QoL.

In conclusion, the study results confirm transient benefits with respect to Physical Functioning and Bodily Pain in the first months after PTA. Improved haemodynamics after PTA did not translate into measurable benefits with regard to the primary endpoints of the study at two years.

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