Reviewer’s report

Title: Conservative treatment of idiopathic scoliosis according to FITS concept: presentation of the method and preliminary radiological and clinical results respecting SOSORT and SRS criteria.

Version: 2 Date: 27 August 2011

Reviewer: Manuel Rigo

Reviewer’s report:

This is my second report to this paper (first after first re-submission). As reported previously, the issue is of high interest, considering the current state of the art. As a whole, this paper would deserve to be published, however, only after a better edition of the first version. This reviewer knows about author’s capability to improve the presentation of this present version. Always with a constructive spirit, these are my current recommendations:

1) Abstract is missing in this manuscript
2) Regarding methodology:

The study design should be clearly defined at the end of the introduction section in order to justify the publication of a new 'retrospective cohort showing preliminary results of physiotherapy in comparison with natural history'. The author writes ‘it is the first study based on SRS and SOSORT criteria’. However, this point is at least questionable. First at all, SRS criteria have been recommended for brace studies. SRS criteria are: 1) 10 years of age or older; 2) Risser sign 0-2; 3) Initial Cobb angle of 20º-40º; 4) No previous treatment; 5) Pre-or less than 1 year post-menarche. The outcomes will be reported as the percentage of patients who have < or = 5º; > or =6º at maturity; curves exceeding 45º at maturity and the percentage who had surgery recommended/underwent; percentage of patients undergoing surgery at two years follow-up beyond maturity. There are not SOSORT accepted criteria for studies on the effect of physiotherapy but old guidelines where indication for exclusive physiotherapy, when considering the Cobb angle, would be 15º-25º, however, in combination with the risk for progression based on the progression factor from Lonstein and Carlson. Thus, in the present study, inclusion criteria seem to be a combination of SRS criteria with SOSORT guidelines. Author claims that outcomes are based on SRS criteria whilst this would be only possible considering that all patients reached maturity and a further follow-up of two years is also reported. I would strongly recommend the author to explain at the end of the introduction section that the author has been using her method since 2005 and as a part of a quality control protocol she is retrospectively looking at and reporting (due to its relatively high interest in consideration to the current state of evidence) preliminary results in comparison with natural history cohorts. Then, in the material and methods section, I would recommend to explain exactly which were
the inclusion criteria to define the group A and why these criteria were selected. Descriptive statistics, like showed in table 1 should show at least the SD. Ranges are not obligatory in the table as it would be defined by the same inclusion criteria. Looking at the final number of patients who form the Group A (exclusively treated with FITS), 78 patients, the amount seems high enough to make irrelevant the presence in this present study of a Group B, combining FITS with bracing. This second group B is less in size and, on the other hand, shows outcomes from bracing (bad compliance in any case) in combination with FITS. Results of this second group should be discussed with other studies reporting about patients of similar characteristics. Considering that the objective of the current study is to show the effectiveness of the FITS in preventing progression and improving trunk appearance, Group B is here irrelevant and I would recommend excluding it. Then, looking at Group A, a quite big sample of 78 patients was formed, following some inclusion criteria (which should be clearly defined in the material and methods section). Observational time is reported to be from 1 to 5 years with a certain percentage of patients having completed the treatment (it can be assumed that they reached maturity). It is not necessary to state this if there is not going to be reported and discussed the results of this group independently of the whole sample. This data is irrelevant by itself, it is enough to say that the mean observational time was 2.08 years, otherwise please report independently about this group of mature patients. To compare results of group A with natural history, theoretically it should be necessary that all patients were mature, like in the Lonstein and Carlson paper. However, it can be probably accepted this comparison but only after stating this clearly in the discussion section. When reporting about the final Cobb angle for Group A (A1 and A2), the author is not allowed to write about increase or decrease of the angle but only when reaching a statistical significant difference. For example, the author can write that in Group A1 the final observed Cobb angle decreased, because it did it significantly. However, when reporting about Group A2 it should be written that the final observed Cobb angle did not change significantly in comparison with the initial one. The second part of the outcomes report (following partially SRS criteria) shows the percentage of patients progressing significantly (> or =6º) and those remaining stable (< or =5º). Author even shows the percentage of patients that improved, following the same SRS criteria of a change of > or = -5º. Notwithstanding, this definition of progression or stabilization were applied, looking at the SRS criteria, in cases where the initial Cobb angle was 25º or higher. From a clinical point of view, it is questionable that a change of 5 degrees is enough to define progression in cases where the initial Cobb angle is lower than 20º. In this case, to use the SRTS criteria could mean a negative bias for this study as coming from so low initial values, to progress, for example, 6 degrees, could be, at the end of the day, clinically irrelevant and still considerable a good result, considering that bracing was prevented. This would be true, in any case, only when reporting final results. As a positive bias for the study, patients showing no significant change, for example 4º, could be progressive cases when observed for a longer time. This is the main problem of reporting only about a Cobb angle at the end of the observational period, when this period is not divided by protocol in sub-periods of equal time (6 months).
Accepting these limitations (all this should be discussed in the proper section as weak points of the study), the incidence of progression for the whole Group A (11.5%) is still very far from the expected progression at maturity. The expected progression of the whole sample (Group A) could be easily calculated by using the progression factor from Lonstein and Carlson as the necessary parameters (initial Cobb angle, Risser sign and chronological) are properly reported. Although the factor cannot be used individually to predict progression, it could be useful to predict the incidence of progressive cases for a particular sample. The expected incidence of progression in Group A could be defined thought out the progression factor as 30%. Thus, at the time of the observation, the observed incidence of progression (11.5%) is 1/3 of the predicted at maturity. This is good result enough to be defended but only being very rigorous in the discussion and realistic in the conclusions. These results will never allow the author to make any final conclusion, and the way it is written the conclusion could be more realistic. For example conclusion 1) would be more realistic written like follows: ‘Preliminary results suggest that FITS could be an effective treatment, capable to alter the natural history of mild idiopathic scoliosis. Further studies are necessary showing results at maturity and beyond maturity’.

How reliable is clinical assessment? Although the examples are clearly showing a clinical improvement (and this is very important considering that other studies shows numbers from theoretically reliable methods but not pictures - so clear prove-) , outcomes should be based on reliable methods of measurement. How sure is the author about reliability of her methods?.

3) Regarding terminology. The terms 'mild' and 'moderate' in relationship with groups A and B respectively, are used properly at the end of the paper. However in the introduction, the author use the terms low moderate and high moderate for scoliosis under 30º. Although there is no a consensus on theses terms and there is no an accepted classification using such a terminology, in most of scientific papers on scoliosis, scoliosis under 30º is called 'mild scoliosis'. Is better not to use first person in scientific papers but third: for example 'the author finds these results...' instead of 'I find these results...'

4) Patients with 10 years of age were included so it should be written that age was > or = 10 years and not 'patients were older than 10 years'.

5) In pg 16 it is written Group B (27 patients, scoliosis of 26º-4º). Please clarify. In any case, this reviewer recommends leaving Group B.

6) English style: although I am is not a native speaker, some expressions and constructions sounds strange when compared with other scientific papers. Edition of the English style by a scoliosis/native speaker expert would be probably desirable.

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
'I declare that I have no competing interest'