Reviewer's report

Title: Discontinuation of Thyroid Hormone Treatment Among Children in the United States with Congenital Hypothyroidism: Findings from Health Insurance Claims Data

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Reviewer: Antonella Olivieri

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In this article the Authors describe the rate at which children diagnosed with congenital hypothyroidism (CH) discontinue thyroid replacement therapy in early childhood in US. They find that about 40% of the examined sample had treatment discontinued inappropriately (by 36 months of life), with potentially long-term harm for at least some children with permanent CH. Although this study has several limitations (lack of information on laboratory tests and imaging results, co-pays for prescriptions, etc.), the Authors pose a relevant question on the adherence to available guidelines for clinical management of babies with CH.

However there are some comments to be made.

Major Compulsory Revisions

1. Table 1 shows a high frequency of discontinuation of treatment within the first 6 months of life, ranging between 5% and 15%, in both databases. In the Discussion section the Authors hypothesize that this rate may be due to babies in whom treatment was begun only on the basis of preliminary tests results and then stopped after confirmatory tests ruled out CH. However they do not show any evidence to support this hypothesis. Is the F/M ratio approximately 1.0 among these babies? If yes (as probable), such a result would further support the hypothesis that not confirmed cases discontinued treatment so early.

2. Table 1 also shows a higher period-specific discontinuation rate before 24 months in the Medicaid sample than in the Commercial sample. The Authors report this finding in the Discussion section, although it is more proper to include it in the Results section. In the Discussion section the Authors should rather try to explain this difference. Do the Authors consider expected or unexpected this finding? Do they think that socio-economic factors or a different training of physicians/pediatricians who followed these babies can play a role?

3. In the Discussion section the Authors state that they are concerned “that an important number of children for whom treatment was discontinued likely had permanent CH” (pag.12, lines 6-7). However, also in this case they do not show any evidence to support this hypothesis. It would be interesting to analyze imaging results to have an idea of the frequency of CH children with thyroid dysgenesis who discontinued the replacement therapy inappropriately, even though these data are incomplete. In fact, in the Method section they state that
either specific laboratory tests or imaging studies are “not always properly coded within the databases”. This sentence seems to suggest that at least partial information is available. It has been really impossible for the Authors to perform an analysis on a subgroup composed of CH children for whom imaging results are reported in the databases? To have an adequate number of cases to analyze, and given the similarity in findings between the databases (approximately 40% of inappropriate discontinuation), you can create this subgroup putting together information on imaging results recorded in both databases. In other words: about 280 children diagnosed with CH discontinued treatment by 36 months of life. How many of these children had imaging results? And among these, how many had thyroid dysgenesis?

Minor essential revisions

1. Some spelling mistakes are present in the text: pag.5, line 14 = Centers for Disease Control; pag.7, line 7 = last claim is filed.

2. Reference n.16 reports “paper presented at ....”. The Authors do not indicate a web site where this paper is available or an abstract book. Some details should be given.

Discretionary Revisions

1. In the Conclusions section the Authors underline the importance of developing a surveillance system to evaluate health services delivery and health outcomes for CH children. However they do not suggest any concrete action to improve adherence to available guidelines. If they have some suggestions, it would be very useful to add these in the Conclusions section.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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 interests