

Minutes digital IPSCSG biannual meeting

Date 16 June 2020

Agenda:

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|--|---------------------------|
| 1. Minutes meeting October 2020 | Cyriel Ponsioen |
| 2. 6 th Biennial IPSCSG Meeting London | Doug Thorburn |
| 3. News and proposals from the Working Groups: | |
| • CCA update | Luca Fabris |
| • Liver Transplantation | |
| 1. recurrent PSC project | Palak Trivedi |
| • Natural History, Biomarkers, Clinical Trial Design | |
| 1. FICUS update | Olivier Chazouillères |
| 2. IPSCR update | Cyriel Ponsioen |
| 3. CALiD update | Chris Bowlus/Cynthia Levi |
| 4. Retrospective DB: current projects | Tobias Weissmüller |
| 5. Retrospective study on endoscopic management of PSC | Joshi Deepak |
| 6. Pregnancy and PSC | Joshi Deepak |
| 7. Tofacitinib in PSC: case series | Ida Schregel |
| • MRI | |
| 1. Update workshop | Annika Bergquist |
| 2. AI for diagnosis using MRCP | Fabian Westerhäuser |
| 3. Dominant/relevant strictures | Sarah Poetter |
| 4. Rotations / SC discussion report | Ulrich Beuers |
| 5. Other | Cyriel Ponsioen |

Ad 1.

The minutes of the October 2020 digital meeting were arrested without further comments.

Ad2.

Doug Thorburn does not think a face-to-face meeting will be feasible in September due to COVID. He proposes that it will be postponed to June 2022. Christoph Schramm mentions that the EASL is hosted in London in April, so maybe the two meetings could be combined. Doug and Cyriel mention that this may be too long away from home for many people. Orem Shibolet asks for a hybrid meeting, so that members who cannot come to London can take part. Doug mentions that the face-to-face feature is essential for the spirit of the group, but facilities for online participation can be strived for. In summary: probably the meeting will be held in June 2022, Doug will fix a date.

Ad 3.

CCA WG:

33 institutions contribute to the European CCA registry currently, a similar registry is now rolled out in Latin America (10 institutions).

Animal models: Mdr2-KO mouse with TAA developed typical PSC like biliary lesions.
Luca Fabris is in need of new patients/samples of human intrahepatic CCA with PSC and without PSC.

Cyriel encourages Luca to advertise on the current studies page of the IPSCSG website.

Liver transplantation WG:

Palak demonstrates the Redcap database, which is ambispective (both retrospective and prospective). Data may be sent and uploaded in Redcap after data transfer agreement forms are signed. Cyriel asks how data is entered. This can be done by a contributor him.herself or by sending a database, e.g. Excel file to Palak.

Main questions to answer with the registry: risk factors for recurrent PSC, risk factors for graft survival/outcome, colectomy type and timing. Cyriel again recommends to put the project on the website for advertisement.

Natural History, Biomarkers, and Clinical Trial Design WG:

1. FICUS

Olivier gives an update on the FICUS study, follow up period is almost finished. He hopes to present the final results next year. The biobank samples may be used for various study proposals. COViD-19 has caused a serious pushback in the amount of data that have been entered, but hopefully this can partly be caught up.

2. IPSCR

Cyriel gives an update on the International PSC Registry. Much effort currently goes into drawing an overarching umbrella consortium agreement and DTA/MTAs that describe the general principles, but do not go into specific details that may be slightly different in various participating countries. Currently in total 2964 patients are available with retrospective data, 718 patients are being followed prospectively, and 400 patients are entering PROMs regularly.

3. CALiD

Currently 20 sites, 2 pending. Over 1000 patients enrolled. 10 years retrospective, 5 years prospective. Cynthia alludes on their study regarding PSC in African Americans. Itch-PSC study is mentioned, which is a retrospective, cross-sectional and prospective study. Investigating overall itch.

Furthermore, a study is planned to test the recently developed PSC PRO questionnaire and the 5D-Itch scale in 500 PSC patients.in PSC. Currently CALiD is not routinely collecting PROMs.

4. Retrospective DB: current projects

Tobias gives an update on the retrospective database and various sub-studies. Currently, the retrospective DB contains 12649 individual datasets from several DBs. A manuscript on the Impact of Geographical Region and varying Patient Management Strategies on Transplant-free Survival and Malignancy Risk in Primary Sclerosing Cholangitis is almost completed and will be circulated soon. Three other projects have finished recruitment: 3 projects finished recruitment: One on surveillance strategies, one on dominant strictures, and one on the management/outcome of CCA.

5. Retrospective study on endoscopic management of PSC

Joshi reports that the original plan to study outcome of therapeutic ERCP in advanced PSC patients has shifted towards a proposal to look at the role of ERCP in all PSC patients. Study aims include indications for ERCP, choice/role of AB pre and post ERCP, complications, outcomes, and others as the role of cholangioscopy. Annika proposes to liaise with the MRI working group as diagnostics are pivotal for the indication of ERCP. Other high volume centers are invited to join.

6. Pregnancy in PSC

Pregnancy outcomes in PSC in a broad sense (fetal outcomes, pruritus management, etc. are the main study aims of this project. Analysis will start in September, if any centers are interested they can contact j.nayagam@nhs.net as soon as possible. Currently 17 centers are interested.

7. Tofacitinib in PSC: case series

Ida gives an update on the tofacitinib study. 42 patients are currently included. Colitis improved in the majority (not sign). ALP and total bilirubin did not decrease significantly. Manuscript will follow end of summer.

MRI WG:

1. Annika provides an Update workshop

Homepage is updated with all details about the ongoing projects. She also introduces a nice template that can be used for uploading any new study protocol on the current studies/proposals page on the IPSCSG website.

Hopefully a face-to-face meeting can be organized in the Fall of 2022.

2. AI for diagnosis

Fabian alludes on a German AI project. Centers are still welcome to join; both MRI and metadata on PSC patients and controls are welcomed. Fabian will update the study information and his contact details on the homepage. Martti mentions that the definition of PSC is important, especially if one wants to include MRI's of early PSC also. Christoph explains that early MRI's in PSC can be included retrospectively when clinical diagnosis of PSC is made according to the EASL criteria.

3. Dominant/relevant strictures

Sarah Poetter gives a short presentation on a Viennese dominant strictures/relevant strictures project. External validation is needed.

Ad 4.

Ulrich gives a brief summary of the recent Steering Committee meeting.

Tom Karlsen has launched an initiative together with Ricky Safer from PSC Partners for Cure to a virtual meeting to exchange experience with natural history registries, which is welcomed by the SC. Among the SC there is broad optimism about the future of the working groups. There is concern however on the experimental models WG. One proposal was put forward to organise a one- or two-day workshop among IPSCSG members on animal/experimental models, either in conjunction with the Biennial Meeting in London or

separately. The idea of one or two flagship projects that will promote collaboration among the group was mentioned. With regard to administrative issues the SC agreed and proposed to the group that the secretariat stays in Amsterdam until the June 2022 London Biennial Meeting. Also, rotations of SC members and WG leads are deferred to June 2022.

Ad 5.

Cyriel mentions that there are no further issues to be discussed. He encourages everybody to put their proposals for studies on the website using the nice template designed by Annika et al, by sending this to Hadassa via jpscsg@amc.uva.nl

Next meeting in October/November, either face-to-face in California during AASLD or virtual again, to be decided later.

June 17, 2021

Cyriel Ponsioen

Bregje Mol