

Experiences of CSF collection by serial sampling or lumbar puncture in clinical pharmacology research

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BACKGROUND

Cerebrospinal fluid (CSF) collection is a valuable source of information for studying PK and PD of drugs targeting the CNS. QPS routinely applies this methodology and here we share our recent experience.

METHODS

- Identification of internal studies in which CSF was collected
- Per study, population, number of subjects, type of collection, purpose of collection and procedure related adverse events were recorded

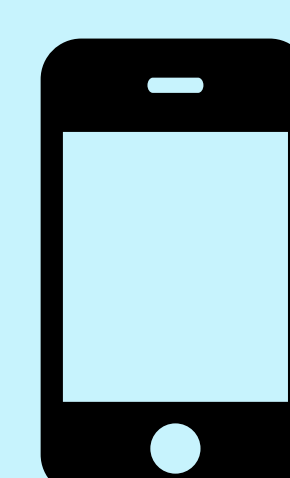
RESULTS

- 15 studies with CSF collection.
- 8 studies with 1-7 LPs per subject.
- 7 studies with serial sampling up to 36 hours
 - › 2 of these studies with twice serial sampling within the same subject
- 11 studies with in total 91 healthy volunteers
- 4 studies with in total 14 Alzheimer patients
- 5 studies for PK reasons only
- 10 studies for both PK and PD
- Post-dural puncture headaches were rare

CONCLUSION

- CSF sampling can be safely implemented in clinical pharmacology studies
- Serial CSF sampling can be done twice within the same subject

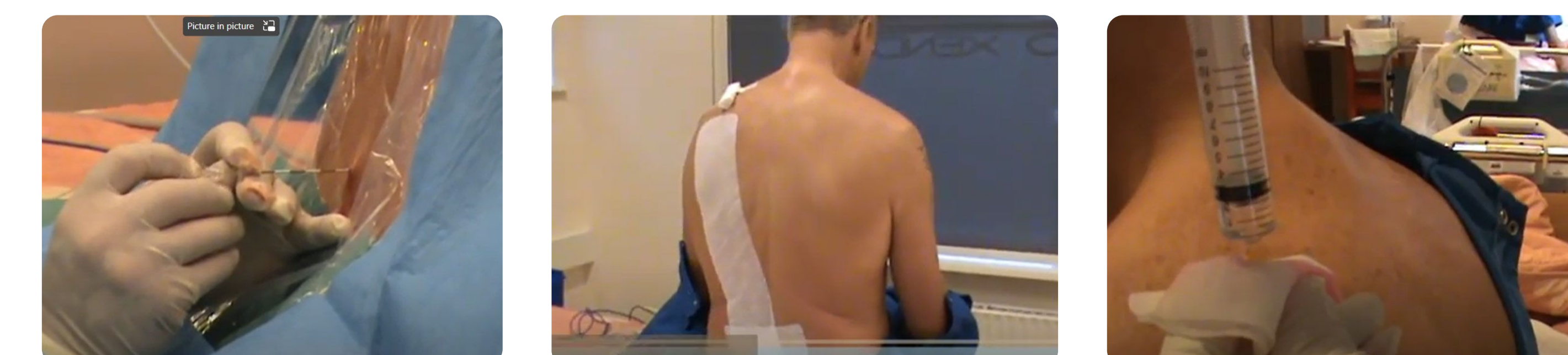
Cerebrospinal fluid collection in clinical pharmacology research:
Invasive but safe and invaluable for biomarker and pharmacokinetic research



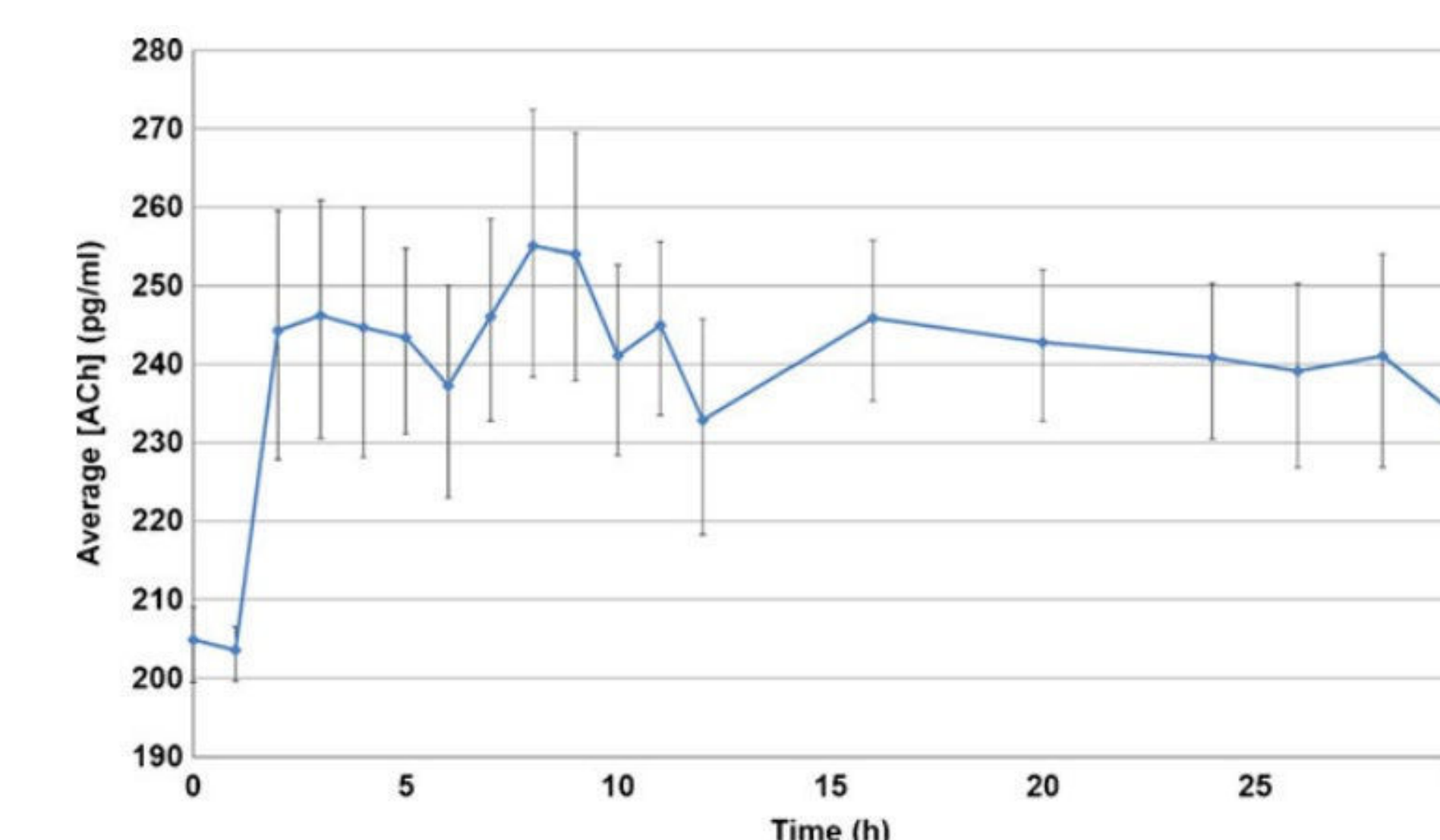
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Insertion of canula, ready for sampling and actual sampling



Mean CSF Ach concentrations in n=7 healthy subjects



Example of twice plasma and CSF collection (on Day 1 and Day 25) within the same subjects

