HEMODIALYSIS WITHOUT AN EXTRACORPOREAL BLOOD CIRCUIT? MODULAR DESIGN CAN MEET PATIENT PREFERENCES & STANDARDS

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Methods

The term "hemodialysis" (HD) as defined by international standard IEC 60601-2-16 was used in a PUBMED database query regarding (trans)portable, wearable and (partly) implantable HD systems. 24 out of 159 search results were included and scanned for specific HD devices and/or HD systems in development. We collected additional information about weight, size and development status via the internet and/or by contacting manufacturers. IATA hand baggage criteria formed the border between transportable and portable. Technology Readiness Levels (TRL) values were assigned by combined TRL-scales of the European Union and NATO medical staff. See also Fig. 1.



Figure 1: PUBMED query to identify Hemodialysis Systems (or large R&D projects towards them).

Results

The query revealed 13 devices/projects: 7 transportable (6xTRL9, 1xTRL5); 2 portable (1xTRL6-7, 1xTRL4); 2 wearable (1xTRL6, 1xfrozen); and 2 partly implantable (1xTRL4-5, 1xTRL2-3). See also Fig. 2.

Three main categories of technical approaches were distinguished: Single-pass, Dialysate regenerating, and Implantable HD filter with extracorporeal dialysate regeneration (in climbing order of mobility). Simplified "typical" system diagrams were derived for these three main categories of typical approaches. Two of these diagrams are depicted in Fig. 2. Technical trade-offs are dominated by water consumption/reclaim, HD filter technology and connection to the vascular system.



Figure 2: Graphical summary of findings. Presently, single pass systems dominate the market (left diagram). Dialysate regenerating HD systems allow further miniaturization and are in clinical trials. With an implanted HD filter, the blood can stay inside the body and only an extracorporeal dialysate circuit (preferably with dialysate regeneration) is needed (right diagram).

Discussion

Compared to Single-pass HD systems, dialysate regenerating HD systems offer a first miniaturization step towards truly portable (or even wearable) HD devices that meet IATA requirements for airplane hand luggage [1]. Such HD systems are in clinical trials for market approval. Ongoing R&D projects, aimed at combining miniaturized implantable HD filters with an extracorporeal dialysate regenerating circuit look promising and the principle falls within the scope of hemodialysis as defined in the IEC60601-2-16 standard.

Conclusions

Dialysate regeneration is an enabler for increased portability/wearability of HD systems. In combination with ongoing R&D projects, targeting long-term implantable HD filters, HD without needles or intravascular catheters seems a technical possibility [2]. But lack of funding severely hampers progress in the field of Kidney Replacement Technologies.

References

- 1. IATA passenger baggage rules. https://www.iata.org.
- 2. Ramada DL et al. Portable, wearable and implantable artificial kidney systems: needs, opportunities and challenges. Nat Rev Nephrol 2023;19:481–90.

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