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IMPLANTABLE BLADDER PRESSURE SENSORS IN A CHRONIC ANIMAL MODEL

Hypothesis / aims of study

Conditional electrical stimulation of the dorsal genital nerve, applied at the onset of an involuntary detrusor contraction can suppress the involuntary detrusor contraction [1]. This prevents both high transient pressures and incontinence episodes. It has been shown in an acute animal model that implantable pressure sensors placed in the bladder wall can be used to detect the onset of bladder contractions [2]. The aim of this study was to investigate whether similar pressure sensors could be used to detect the onset of contractions in a chronic animal model.

Study design, materials and methods

Chronic experiments were performed in minipigs to obtain both intravesical pressure and pressure in the bladder wall simultaneously during bladder contractions evoked by artificial filling of the bladder. One pilot experiment and an additional four experiments were performed. An abdominal midline incision was made to expose the bladder. Pouches were made in the middle of the detrusor wall, one on each lateral aspect of the bladder near the dome. Sensors were placed in these pouches, and they were closed by string purse sutures. In three experiments wires from one sensor were tunnelled to the back of the pig and brought through the skin, remaining wires were placed uncoiled in subcutaneous pouches. Sensors were encapsulated with silicone in a two-part moulding process, so that they were lens shaped with a diameter of 13.6 mm and height of 2 mm. Further details have been described previously [2]. Experiment duration was four weeks to three months. Weekly follow-up experiments were conducted in the pigs with transcutaneous leads. A double-lumen intra-urethral catheter was placed in the bladder, and a reference pressure sensor connected to one lumen. The other lumen was connected to an infusion pump set at a rate of 16.7 ml/min (pump max). The maximum infused volume was set to 400 ml. Contractions evoked by filling distension were recorded. In the terminal experiment, all pigs had a cuff electrode placed on the pelvic nerve, and recordings of contractions evoked by electrical stimulation were performed.

Results

In the experiments with transcutaneous leads, four of six sensors stayed in place. In the experiments with fully implanted sensors, one of four sensors stayed in place. In the pilot experiment severe corrosion was observed. This was reduced in the remaining experiments by adding a thin layer of silicone by dipping in a low-viscosity dip-coat solution. These findings are summarized in table 1. In the pilot experiment contractions were evoked by artificial filling. Figure 1 shows a recording of such a contraction. An automatic onset detection algorithm [2] was applied to the signals; detection using the wall signal was delayed by 1.9 s (and 1 cmH_2O; 12.7 cmH_2O vs. 11.7 cmH_2O) compared to using the intravesical pressure. Bladder compliance was 37 ml/cmH_2O in the shown recording. In the additional experiments, bladder contractions could not be evoked. Reliable signals could be obtained from the sensors for up to three weeks, but not for any longer. Hence, the terminal experiments were not performed, but bladders were dissected out and fixated in formalin for closer visual inspection.

Interpretation of results

Two primary problems became evident from the experiments. One was the reliability of the implantable sensors. This is believed to be caused by insufficient encapsulation, as the tracks and contact pads of the sensors were only encapsulated by silicone. A sensor designed for implantation, instead of one modified for implantation, is expected to improve or solve this part. The other was the erosion of sensors. From the obtained bladders it was found that the sensors were generally not placed in the middle of the wall as attempted, and in addition that they were not aligned with the wall. Both factors are believed to affect the erosion rate negatively. Having the implantation done by an experienced surgeon may improve this result.

Concluding message

It was shown by one experiment that monitoring of bladder activity, using an implantable pressure sensor, is possible in a chronic setting for up to three weeks. The signal obtained could be used for automatic detection of the onset of contractions. However, reliable signals could only be recorded for up to three weeks. Hence, improved sensors are needed, and further studies are needed to assess the chronic stability of such sensors.

Table 1. Position of recovered sensors and their level of corrosion. None of the eroded sensors were recovered; hence their corrosion level could not be assessed. This is noted n/a in the table. The pilot study had transcutaneous leads from one sensor. Experiment duration is noted in parentheses.

		Position		Corrosion	
#		1st sensor	2nd sensor	1st sensor	2nd sensor
1	Pilot study (6 wks)	in place	eroded	severe	n/a
2	1st w/leads out (4 wks)	in place	in place	minor	minor
3	2nd w/leads out (4 wks)	in place	eroded	minor	n/a
4	1st fully implanted (3 mth)	inside bladder	eroded	minor	n/a
5	2nd fully implanted (3 mth)	eroded	eroded	n/a	n/a

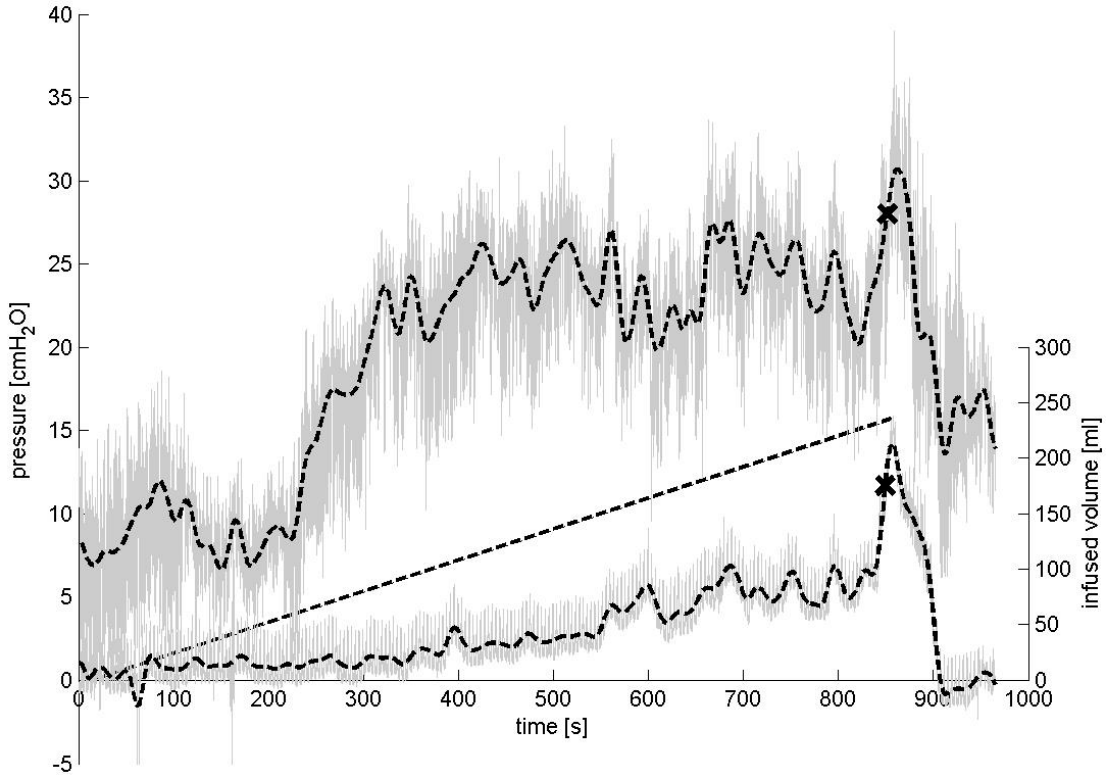

Figure 1. Recording of one successful filling experiment. Top trace is the bladder wall pressure, bottom trace is intravesical pressure. The straight line is the infused volume, according to the scale on the right-hand side of the graph. X's mark the points of onset detection by the automatic detection algorithm.

References

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