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Protocols to compare infusion distribution of wound catheters

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ABSTRACT

Multi-holed wound catheters are increasingly used in clinical practice to administer analgesic/anaesthetic locally to the painful region. The distribution of flow infused during controlled (continuous or intermittent) administration of medication is believed to be an important issue for successful pain relief. Nevertheless, this information is not available from the literature. In this paper, we propose protocols to screen the performance of wound infusion catheters in the laboratory environment. Four wound infusion systems (PAINfusor by Baxter, OnQ Pump with Soaker catheter by I-Flow, PolyFuser Polymedic by Temena and Infiltralong by Pajunk) have been tested. Test results demonstrate that the distribution of the infused flow is different for the four catheters and closely connected to the catheter design (i.e. hole size and position, lumen diameter). Catheters characterized by small size holes (e.g. Baxter, Pajunk) distribute the flow more homogeneously than catheters characterized by large size holes (e.g. I-Flow, Temena). The distribution of infused flow does not change significantly during continuous or intermittent infusion.

1. Introduction

Wound infusion systems are increasingly used in clinical practice for pain management and regional postoperative analgesia [1,2]. Wound infusion kits are composed of (i) the catheter, a closed-end, thin hollow tube with side holes in the distal part (infusing region) and (ii) the infusing device (either an elastomeric or an electronic pump). The catheter is placed in the wound at the end of surgery before closure and local analgesic/anaesthetic is administered continuously in the wound area. Some days after, once the treatment is completed, the catheter is removed.

Infusion systems differ in configuration (type of infusion pump, catheter design) and price. Currently, no objective method is available to evaluate their performance and to support clinical choices between the different systems. The objective of this work is to develop protocols and to screen the performance of four infusion systems in the laboratory environment, under controlled conditions.

The distribution of infused medication (infusion pattern) is believed to be an important issue for successful pain relief: catheters with multiple holes might provide a wider area of infusion and a larger spread of local anaesthetic into the wound. Even if there is still no clinical evidence in this sense [3], previous studies performed in vitro using multi-hole catheters (epidural catheters with three holes) have shown that, even for very simple configurations, the infusion pattern may change significantly depending on the specific pressure waveform generated by the infusion device [4]; the infusion pattern may also change during continuous infusion at typical hospital conditions and during the infusion of manual boluses (i.e. patient controlled intermittent infusion) [5]. The relationship between the infusion pattern produced by the catheter during intermittent boluses or continuous infusion of local anaesthetic and pain relief is even more unclear [6], since the characteristics of the environment in which the catheter is infusing (the epidural space or a wound) may play a significant role.

From the patient/clinician view point, the therapy should deliver the prescribed quantity of local anaesthetic with the specific infusion pattern demanded by the painful region. This objective could be met by the clinician if the infusion pattern produced by the apparatus was known. As discussed by [3], it is not straightforward to associate the optimal type of catheter to the infusion pattern produced "in vivo" due to inherent difficulties of performing these experiments. In this work, we developed protocols to measure, "in vitro", the distribution of flow delivered by a catheter either under continuous or bolus infusion. The laboratory measured flow rates and distribution may not match real "in vivo" infusion patterns, however, the objective characterization of catheters is necessary to set up systematic and repeatable clinical trials.

We developed the protocol and tested four wound infusion systems used in European hospitals (PAINfusor by Baxter, Infiltralong by Pajunk, On-Q PainBuster with Soaker catheter by I-Flow and PolyFuser by Temena). Results show that catheter design is very

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important to control the infusion pattern produced "in vitro" and might be important also to control infusion pattern produced "in vivo".

2. Materials and methods

2.1. Basic principles of fluid mechanics

The catheter is a micro-scale flow distributor operating in the laminar regime. In this regime, the pressure drop, ΔP, to infuse the flow, Q, is given by a Hagen–Poiseuille type formula [7]:

$$\Delta P = P(0) - P_{out} = \mu(T) \cdot K \cdot Q$$

where $P(0)$ and P_{out} are the pressure upstream of the catheter and in the outside environment, $\mu(T)$ is the (temperature dependent) fluid viscosity and K is a constant which depends on the specific geometry of the system (internal diameter, thickness, hole diameter and hole spacing). The pressure, generated upstream of the catheter either by an elastomeric or a syringe pump, decreases along the catheter. The pressure drop, ΔP_i, between each point i, inside the catheter, P_i, and the outer environment, P_{out}, will fix the flow, q_i, delivered through each hole:

$$\Delta P_i = \mu(T) \cdot K' \cdot q_i$$

where K' is a function of hole geometry.

The infusion pattern generated by each catheter will be evaluated as the fraction of flow infused along the catheter, q_i/Q (q_i, $i = 1$, N_H, where N_H is the number of holes). The quantity $q_i/Q = f(K'/K)$ depends only on catheter geometry and can be evaluated independently of many test conditions (i.e. fluid temperature, type of infusion device, overall flow delivered). The values of the geometrical constants, K and K' determine the precise variation of pressure along the catheter and the specific infusion pattern that will be generated along the length of the catheter's infusing region. The larger the variation of pressure inside the catheter between the proximal (inlet section) and distal ends (closed tip), the larger the variation in the amount of flow infused by different holes will be [8].

2.2. Wound infusion systems

Wound infusion systems selected for testing were chosen from commercial brands used in European hospitals. From the clinical view point, there are many factors which make one wound infusion system different from another. Clinicians choose the infusion system to use based on the length of the catheter infusing region (chosen according to the specific infusion task to be performed), the type of infusion device (portable, like elastomeric pumps, or stationary, like a syringe pump), the flow rate of medication to be delivered and the catheter strength (i.e. the risk of breaking the catheter when pulling it out of the patient body). We chose to focus on a subset of wound infusion systems manufactured according to different design concepts (different type of infusion device, different catheter material and geometrical dimensions). As shown in Table 1, systems have infusing regions of similar length (12.5–15 cm), but while Baxter, I-Flow and Temena wound infusion catheters are sold with elastomeric pumps, Pajunk's catheter is sold with no specific infusing device. Elastomeric pumps chosen for testing deliver similar flow rates (2–5 ml/h) at nominal conditions and a syringe pump (Flo-Gard Infusion pump, Baxter) delivering the same flow rate (5 ml/h) was chosen to perform the tests with Pajunk's model.

From a fluid mechanic view point, catheter geometrical characteristics should be the most important parameter which control the infusion pattern. Geometrical details of catheters obtained from catalogue information and from the microscopic analysis of a few samples are shown in Fig. 1. The microscopic pictures of lumen sections (a)–(d) indicate that the ratio between the lumen diameter and outer diameter is 65% for Baxter, 50% for I-Flow, 53% for Temena and 71% for Pajunk. Fig. 1(e) and (f) shows the geometrical characteristics of infusing holes, such as outer diameters and spacings. Two of the systems (Baxter and Pajunk) are characterized by a large number of small, equally spaced infusing holes; the other two (Temena and I-Flow) use a smaller number of larger holes to deliver the flow. The variability in the hole size is larger for the larger holes, obtained by mechanical methods, than for the smaller holes, obtained by laser micro drilling. The system with the largest holes (I-Flow) is equipped with an internal porous membrane.

2.3. Testing protocols

2.3.1. Qualitative evaluation of infused flow distribution

Visualizations of infused flow distribution were made as sketched in Figs. 2(a) and 3(a). The catheter was submerged in a fixed position in a water tank and primed using a 5 ml syringe filled with distilled water. Colored water was infused during the tests

Table 1
Main characteristics of wound infusion systems chosen for benchmark comparison: data of infusing device and geometrical characteristics of catheters.

	Comparison among wound infusion systems			
Brand	Baxter	I-Flow	Temena	Pajunk
Infusing device				
Recommended in kit	LV5	On-Q PainBuster	PolyFuser	Any pump
Used for test	LV5	On-Q PainBuster	PolyFuser	Baxter Flo-Gard
Type	Elastomeric	Elastomeric	Elastomeric	Syringe
Flow rate[a] [ml/s]	5	5	2	5
Catheter				
Nominal diameter, Dc	19G	20G	20G	19G
[mm]	1.067	0.908	0.908	1.067
Measured diam.[b] [mm]	1.015 ± 0.025	1.094 ± 0.025	0.896 ± 0.002	0.985 ± 0.004
Lumen diam.[b] [mm]	0.635 ± 0.025	0.532 ± 0.003	0.4879 ± 0.011	0.0707 ± 0.010
Hole diam.[b] [μm]	34.9 ± 4.63	360.24 ± 35.11	282.56 ± 54.10	70.04 ± 7.79
Hole spacing[b] [mm]	3.653 ± 0.042	4.820 ± 0.088	4.203 ± 0.464	2.455 ± 0.029
N. holes	40	25	12	60
Infusing region [mm]	150	125	150[c]	150
Flow section [mm^2]	0.317	0.223	0.181	0.393
Infusion area [mm^2]	0.038	2.548	0.752	0.231

[a] At nominal conditions for elastomeric pumps.
[b] Data not statistically significant: multiple measurements made based on one sample catheter from each catheter model.
[c] 120 mm according to catalogue.