

## 4 Continuous ambulatory peritoneal dialysis delivery systems

### Guidelines

A. Double-bag systems should be preferred, because they are more efficient in preventing peritonitis in CAPD patients.

(Evidence level A)

B. If double-bag systems are not available, any alternative Y-set system should be preferred to any spike system, again because of more efficient prevention of peritonitis.

(Evidence level A)

C. Although disinfecting devices have not demonstrated any significant reduction of peritonitis rates obtained by double-bag or Y-set systems, they are recommended for patients who have to use a spike system.

(Evidence level A/B)

### Commentary on Guideline 4: continuous ambulatory peritoneal dialysis delivery systems

#### General commentary

Peritonitis and exit site infections are serious complications of peritoneal dialysis and frequent causes of technique failure requiring transfer to haemodialysis. One of the most important points, in the every day practice of continuous ambulatory peritoneal dialysis (CAPD), is the bag exchange procedure during which different microorganisms can enter into the peritoneal cavity via the transiently open delivery system and cause peritonitis. Hence, the delivery system becomes very important in preventing peritonitis in CAPD patients.

The basic aims of any CAPD delivery system should be:

- security—in terms of prevention of peritonitis
- simplicity—in terms of management by the patient or assistant
- quality—in terms of materials (resistant, biocompatible, disposable, recyclable).

CAPD delivery systems available in Europe today include the following.

Non-disconnecting systems:

- collapsible bags with a simple spike (or Luer lock device)

- collapsible bags with a simple spike and germicidal ultraviolet (UV) chamber
- collapsible bags with a simple spike and thermoclave

Disconnecting systems (incorporating the ‘flush before fill’ procedure)

Y-set systems

O-set systems (a subclass of the Y-set systems)

Double-bag (or twin-bag) with Y-set systems

UV flash<sup>®</sup> system (Y-set sterilized by UV light)

ANDY<sup>®</sup> system (Y-set system)

ANDY<sup>®</sup>-Plus system (double-bag Y-set system)

Stay-Safe<sup>®</sup> (ANDY<sup>®</sup>-Plus + different connection methods)

L<sub>3</sub> fast system

UV Flash<sup>®</sup> is a registered trademark from Baxter.

ANDY<sup>®</sup> and Stay-Safe<sup>®</sup> are registered trademarks from Fresenius AG.

Materials used in the composition of CAPD systems include:

- Polyvinyl chloride
- Clear-Flex<sup>®</sup>
- Biofine<sup>®</sup>

Clear-Flex<sup>®</sup> is a registered trademark from Bieffe-Baxter. The Clear-Flex<sup>®</sup> bag is a three-layer laminate. Its inner layer is composed of polyethylene, the middle of polyamide and the outer of polypropylene.

Biofine<sup>®</sup> is a registered trademark from Fresenius AG. Biofine is a material made up by polyolones, which are polymers constructed from hydrogen and carbon atoms.

Review of the literature reveals that no study has addressed the issue of differences among the various CAPD delivery system materials, in terms of technique failure or patient survival.

Three basic types of delivery (catheter connecting) systems are in use today. In chronological order of their development, they are the simple spike, which was considered as the ‘standard’ system during the 1980s, the Y-set and the double-bag (or twin-bag) system.

In the ‘standard’ system, the catheter is connected to the bag via a piece of tubing and a spike or a Luer lock device. During each bag exchange procedure, the spent dialysate is drained from the peritoneal cavity into the empty bag, which is then disconnected and discarded. A new bag is then connected to the patient’s permanent catheter and the fresh dialysate is introduced into the peritoneal cavity. The empty bag is

rolled up and remains attached to the patient until the next bag exchange (non-disconnecting system). In the Y-set system, the bag is disconnected from the patient between exchanges (disconnect system). During the bag exchange procedure, the main (vertical) limb of the Y-shaped connecting tube is connected to the catheter, while the second limb is connected to an empty (drainage) bag and the third one to a new bag containing the fresh dialysate. In this system, therefore, the first thing that happens, during each exchange procedure, is the drainage of the spent dialysate from the peritoneal cavity into the empty bag. The Y-connecting tubing is then flushed with a small volume of fresh solution drained from the new bag directly into the drainage bag. After this, the fresh dialysis solution is introduced into the peritoneal cavity and the Y-set is disconnected from the catheter. Apparently, with this technique (flush before fill), any microorganisms that happen to be inadvertently introduced into the system are flushed into the spent dialysate. In the early years of the Y-set system, the tubing was rinsed with a hypochlorite disinfectant during bag exchange. In the double (or twin)-bag system which is similar to the Y-set system, both bags (the empty one and the one with the fresh solution) are already connected to the tubing by the manufacturer. Thus, only one connection is required to be performed by the patient: that of the main limb with the catheter.

Not all of the above systems are available in all European countries. It is estimated (personal communication with the major manufacturing companies) that, at present, 90% of European patients are using double-bag disconnecting systems.

#### *Guidelines A and B. Delivery systems and peritonitis*

The accumulated experience, so far, shows clearly (evidence level A) that disconnecting (Y-set and double-bag) systems are superior to 'standard' systems regarding prevention of peritonitis. In particular, in eight randomized controlled trials (RCTs) or quasi-RCTs [1–8], the Y-set delivery systems were compared with the 'standard' systems. In all but one [6] of the studies, the number of patients who experienced at least one episode of peritonitis was significantly less for patients using the Y-set compared with those on the 'standard' system. All the studies showed a significant increase in the number of months in between each episode of peritonitis. Also, in two controlled studies [8,9] where the 'standard' system was compared with the double-bag systems, the results showed a significantly reduced incidence of peritonitis with the latter systems. Finally, in four controlled studies [8,10–12], where the two newer methods, i.e. the Y-set and the double-bag systems, were compared, significantly fewer patients using the double-bag system experienced peritonitis.

In a prospective non-randomized study [13], patients were assigned to different CAPD disconnecting (Y-set, automated peritoneal dialysis) or non-disconnecting

systems (spike, UV connection device) according to clinical and lifestyle criteria. Peritonitis rates were significantly less for disconnecting systems, but there was no difference in exit site infection rates. Two (evidence level B) studies showed no difference in peritonitis rates between UV-flash and disconnecting systems [14,15]. One of them [14] additionally showed that the incidence of peritonitis of these two systems was significantly less than that of the 'standard' system. The length of the branches of the Y-set systems, in one study [16], was not related to the incidence of peritonitis.

*Delivery systems and exit site infection.* In seven RCTs, the incidence of exit site or tunnel infection is not significantly affected by the delivery system. In particular, four studies comparing the Y-set with the 'standard' system [4–7], two studies comparing the double-bag with the Y-set [11,12] and one study comparing the double-bag with the 'standard' system [9] demonstrated no significant difference either in the number of patients who experienced exit site or tunnel infections, or in the number of patient-months on CAPD per episode of exit site infection.

#### *Guideline C. Disinfecting devices*

Disinfecting devices such as UV-flash [14,15], as well as microwave moist-heat [17] and xenon-based UV light, although effective *in vitro* [18], have not demonstrated improvement of peritonitis rates obtained by disconnecting systems. The results of the study by Kubey *et al.* [19], who quantified bacterial removal in Y-set and double-bag systems, emphasize the importance of the design of the fluid path flow (flush before fill) in the overall safe performance of these peritoneal dialysis systems.

## References

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