NEFROLOGIA. Vol. XIII. Núm. 1. 1993

Y system with in line disinfectant or disposable Y set with no disinfectant? This is the problem

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Introduction

In the past years the large majority of peritonitis episodes in patients treated by Continuous Ambulatory Peritoneal Dialysis (CAPD) were caused by bacteria coming from the environment which penetrated into the set during the exchange. These contaminations may be a consequence of errors, defects in the system, accidental fractures of the bag, set or catheter Among the bacteria coming from air, skin, mouth or nose S. epidermidis is the most frequent responsible of peritonitis, followed by S. aureus and by other gram positive and gram negative bacteria.

To minimize the risk of exogenous contamination, in the last two decades research has been focused on the possibility to develop an ideal connection system. It should be easy to handle and it should be designed to prevent the risk of touch contamination. In addition the ideal connection system should kill bacteria accidentally entered into the set during the bag exchange. The ideal connector should be designed to wash out bacteria with their toxins and plasticizers, before filling the peritoneal cavity. Finally the connector should not contain any kind of disinfectant which could be accidentally introduced into the peritoneal cavity.

The connections

The standard Oreopoulos system, which involved the wearing of the empty bag was the first effective step in reducing peritonitis rate[1]. A few years later two CAPD systems were proposed by italian investigators. The Perugia Y system[2], consisted of a reusable Y shaped set, connected to the peritoneal catheter, which had to be filled with disinfectant during the dwell time and was connected to the new bag during the exchange. The double bag system[3] consisted of a disposable Y set preattached to the new dialysis bag and to an empty bag which will collect the drained dialysate. This system did not include the presence of in-line disinfectant. Both these systems were further modified in the following ten years (fig. 1) in order to increase safety, improve handling and reduce the number of manouvers.

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The theoretical basis

The theoretical basis of peritonitis prevention by both these systems is the possibility to wash out bacteria contained into the set by the flush of a small amounts of the new dialysis fluid followed by the flush of dialysate drained from peritoneal cavity. In addition the recent double bag derived systems use disposable sterile Y sets, wich exclude the possibility of bacterial growth or biofilm formation at the Y bifurcation during the dwell time. The Y Perugia system is a reusable Y set filled with in-line disinfectant which should kill all the bacteria which could have been introduced into the system. It should be noted that when the disinfectant is introduced by capillarity from a glass containing 50-100 ml of Amuchina, as we do in our Unit, the disinfectant by itself works as a second flush after the exchange. During the dwell time, the disinfectant remains into the set to prevent possible bacterial proliferation. The disinfectant should be still active in killing bacteria at the beginning of the new exchange. Therefore this system associates the effect of a partial flush before filling and the presence of the disinfectant into the set, thus offering an almost complete protection against intraluminal contamination by small amounts of bacteria.

The flush

Both in the Y system and in the double bag derived systems the dialysate outflow washes the outlet branch of the Y. The flush in the inflow branch is limited in the Y system to the small amount of dialysis solution required to wash out the in line disinfectant. The flush at the connecting point of the Y system (the spike) is performed with about 10 ml of dialysis solution, while the connecting point of the double bag derived systems (the luer lock) is washed by the whole amount of dialysate contained into the peritoneal cavity.

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1. Se establece un PREMIO de 350.000 pts. destinado a premiar el mejor trabajo realizado en equipo o individualmente sobre un TEMA LIBRE.

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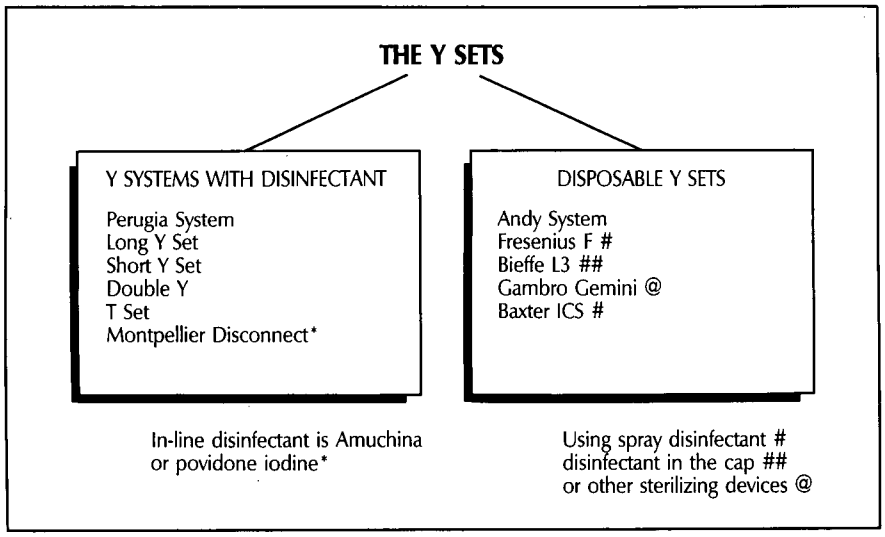

Fig. 1.—List of the most used Y set devices, with and without in line disinfectant.

There are several studies on the effect of flush before filling in preventing bacterial growth in CAPD. Experimental studies showed that flush with more than 100 ml of sterile solution performed immediately after in vitro contamination[4-6], can remove more than 90 % of contaminating bacteria. Flushing is more effective when performed after the immersion of connecting ends into a disinfectant solution[6]. Other studies showed that flush performed a few hours after the contamination can remove all S. epidermidis but only very small percentages of S. aureus and Pseudomonas strains[7,8]. Errors may allow some bacteria to enter the set; they may proliferate during the exchange or the dwell time. The bacterial proliferation can overcome the cleaning effect of the flushing. In vitro studies showed that flush cannot sterilize CAPD sets previously contamined by gram negative bacterial colonies[7,8].

The disinfectant

The use of in line disinfectant in the Y system is based on the possibility that contaminating bacteria can enter the set during the disconnection manouvers (after the flush has been performed) and grow, eventually forming a large number of colonies and biofilm, as shown by in vitro studies[9]. In this case flush might be insufficient to remove all the bacteria[7,10].

The ideal disinfectant should have a wide, prompt and strong antibacterial activity, it should maintain its antibacterial activity during the overnight dwell. The disinfectant should not be inactivated by the dialysate or by the plastic of the tubes. It should not be dangerous to skin and peritoneal cells nor cause damage to the plastic lines. Finally it should be cheap.

Amuchina has a rapid and good bactericidal activity confirmed by in vitro and in vivo studies[4,11,12]. This disinfectant may be inactivated by light, organic materials and glucose containing solutions[13]. If the amount of disinfectant is small and the total amount of glucose is high, inactivation can be clinically relevant. Cantaluppi et al. (unpublished data), showed that concentrations of active chloride in the short Y set decreased after 8 hour in vitro incubation with 3.86 % glucose solutions (fig. 2). The decrease was slower if the amount of glucose solution was reduced from 0.4 to 0.1 ml. We measured active chloride concentration in the spike cap and in the branches of standard Baxter Y set, containihg 15 ml of in line Amuchina (5,500 ppm of active chloride) (fig. 3) and in the cap of the Bieffe L3 system, a double bag derived system (fig. 4), containing 1 to 3 ml of Amuchina (5,500 ppm of ac-

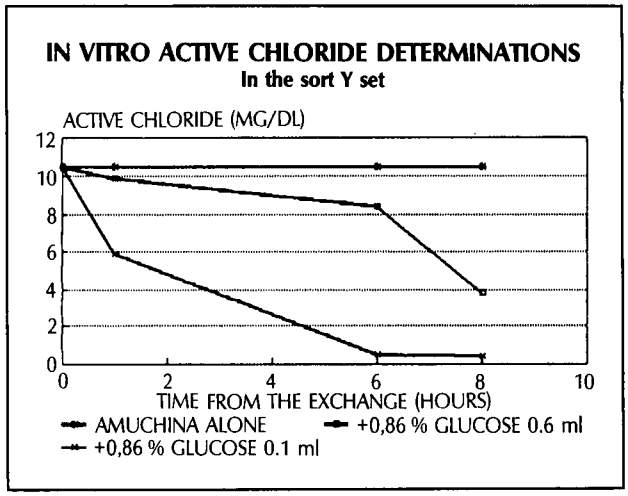

Fig. 2.—Concentration of active chloride in the short baxter Y set at different times after the exchange. Results from an in vitro study, data kindly supplied by dr A. Cantaluppi (Baxter spa).

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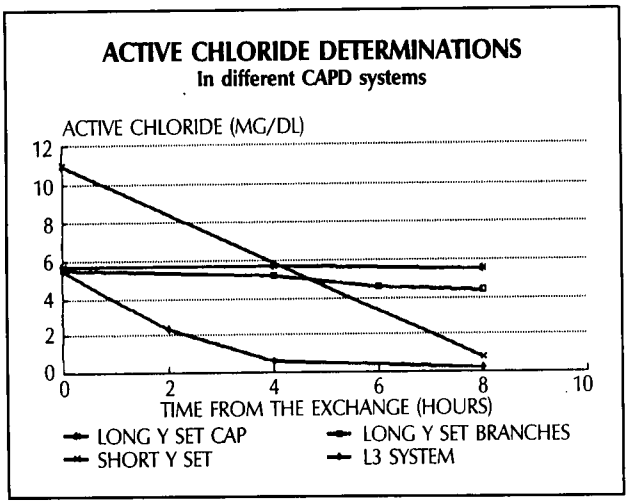

Fig. 3.—Concentration of active chloride in the cap and the branches of the long Y set, in the branches of the short Y set and in the cover cap of L3 luer lock.

tive chloride) in the cap, after different in vivo dwell times with different glucose solutions. In the cap of Y set spike Amuchina was not in contact with the dialysate and its concentration was almost unchanged up to 8 hours after the exchange, while in the other cases the concentration of active chloride decreased (fig. 3). The concentration of active chloride was inversely related to the glucose concentration and to the dwell time (fig. 4). However the results of this study showed that the concentration of the disinfectant should theoretically be sufficient to kill the majority of contaminating airborn bacteria, even after the overnight exchange.

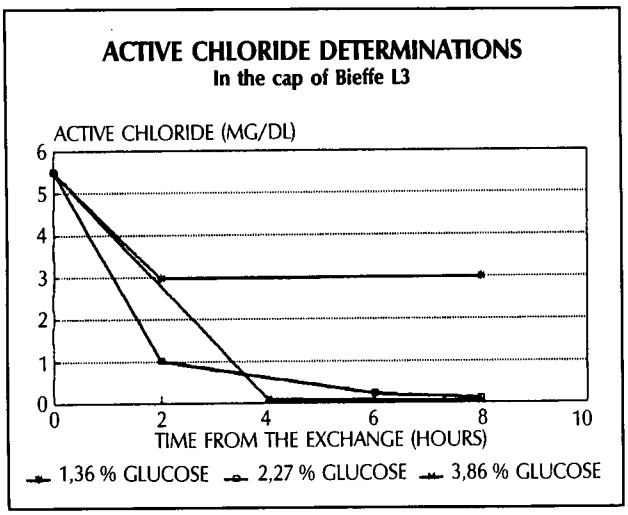

Fig. 4.—In vivo measurements of active chloride in the cap of the L3 system luer lock. Active chloride concentrations were determined after different dwell times with dialysis solutions containing different glucose.

Risks of the disinfectant

The major concern about the use of in line disinfectant is the risk that the disinfectant may accidentally be introduced into the peritoneal cavity during the exchange procedure and may cause severe or irreversible damage to mesothelial cells.

In vivo studies showed that the majority of disinfectants used in clinical CAPD are toxic to mesothelial cells when injected at high concentrations into the peritoneal cavity of experimental animals[14, 16].

Intraperitoneal injection of povidone iodine was largely used to treat peritonitis in CAPD[17] and Amuchina was injected intraperitoneally to treat intraperitoneal surgical abscesses[18]. Buoncristiani[19] reported no negative effects after intraperitoneal injection of Amuchina at low concentration in CAPD patients. In CAPD there are few clinical data about the risk of accidental introduction of disinfectants into the peritoneal cavity, based on clinical symptoms which could be ascribed to this complication. This risk ranges between 1 episode every 4,380 exchanges and 1 every 7,500 exchanges[20, 21].

We reported accidental introduction of Amuchina in 30 of 61 patients treated with the long Baxter Y set and in none of 9 patients using the short Y set[22]. Our data were recorded on the basis of an individual interrogation of the patients, more accurate than a retrospective analysis of clinical records. Many patients spontaneously washed the peritoneal cavity with fresh dialysis solution until pain disappeared, without informing nurses about this complication, that was not recorded.

More recently (De Vechhi et al., unpublished data) accidental introduction of Amuchina was observed in 25/47 patients treated with the long Y set, in 3/11 patients treated with the short Y set and in none out of 17 using the Bieffe L3 system. This complication was not related to patient age, sex or to the time when the exchange was performed. Figure 5 depicts the errors leading to accidental introduction of Amuchina in patients using the Y system. In patients using the long Y set the most frequent error was number 1 (72 %), followed by number 3. All the patients using the short Y set made the error reported as number 4. The short Y set is filled by a syringe containing 10 ml of disinfectant and each brach of the set contains 0.4 ml. The long Y set is filled by capillarity from a glass containing 100 ml of disinfectant: each branch of this set contains 8 ml. It is possible that the amount of disinfectant contained in one of the short Y set branches may cause abdominal pain when introduced into an empty peritoneal cavity (error number 4), but probably this amount is too small and disinfectant is inactivated too rapidly to cause pain when introduced into a peritoneal cavity immediately filled with 2 liter dialysis fluid (error 3). This could

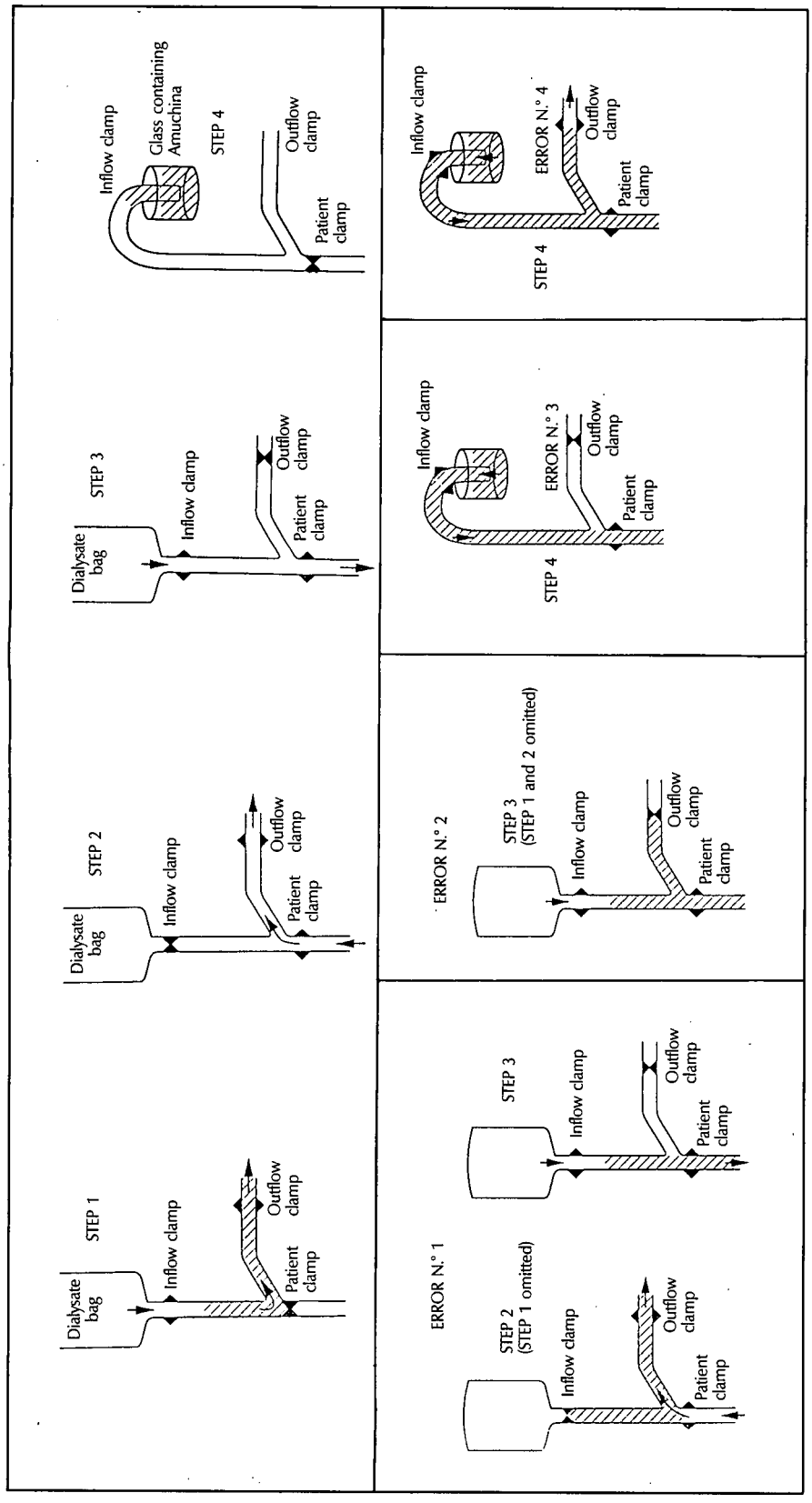

Fig. 5.—Schematic picture of the steps for the exchange with the Y system with disinfectant (above) and of the errors leading to accidental introduction of Amuchina.

explain both the low rate of symptomatic introduction and the type of error involved in the patients using the short Y set. Clinical symptoms of accidental introduction of Amuchina were abdominal pain (100 %), vomiting (22 %) and diarrhoea (10 %); these symptoms disappeared after 1 to 16 exchanges with fresh dialysis solution. No differences in peritoneal equilibration between patients with previous accidental introduction of Amuchina and the others were observed. Only one patient who introduced more than 100 ml of Amuchina (5,500 ppm of active chloride) developed a severe reduction in ultrafiltration which did not disappear during the further 13 week follow up[22].

We cannot exclude the possibility that small amounts of disinfectant are frequently introduced in the absence of clinical symptoms in patients using the Y set or double bag systems containing disinfectant inthe cap. Due to the large amount of Amuchina contained in one branch of the long set, the accidental introduction of disinfectant contained in a branch should be expected to induce abdominal pain. Therefore the introduction of asymptomatic amounts of disinfectant might be caused only by minimal leaks of the system: the quality control and the periodic set exchanges should minimize this risk. At present here are no data confirming the possibility of asymptomatic introduction of disinfectant, and therefore we cannot know the incidence of this complication and its possible effects on mesothelial structures.

It is difficult to know the possible consequences of symptomatic and asymptomatic introduction of Amuchina into the peritoneal cavity. A recent paper[23] reported the morphology of peritoneal membrane, at autopsy of CAPD patients using povidone iodine as disinfectant. Severe chronic inflammation and peritoneal thickening were frequently observed. The incidence and severity of these abnormalities were not related to the duration of CAPD treatment. These data suggest the possibility that CAPD per se can damage peritoneal membrane.

Does the addition of disinfectant reduce the peritonitis rate?

A study investigating possible differences in the peritonitis rates between CAPD patients treated with different systems should include a sufficient number of patients to reach statistical significance with a minimum follow-up as long as the expected peritonitis rate (about 30-40 months). In addition bacteria causing peritonitis should be identified, being prevention from exogenous contamination confirmed by a significant decrease in peritonitis episodes due to S. epidermidis and S. aureus. At our knowledge, none of the published studies on double bag derived systems fullfills these criteria[24-26], being the number of patient small and the follow up too short. In addition few prospective controlled studies compared the incidence of peritonitis in CAPD patients treated with the Y system with disinfectant or with double bag systems. Moreover many double bag derived connections, with disposable Y set, involve the use of small amounts of disinfectant into the cap of the adapter or the use of spray disinfectant at the end of the exchange, thus making any conclusion on the need for the disinfectant unreliable. Therefore, a correct evaluation of the role of disinfectant in preventing exogenous peritonitis, should compare only patients treated with the same Y system, with and without the addition of in line disinfectant. In fact the need for the disinfectant is reduced by the sterility of the inlet branch, by a lower number of connections, by the ease in performing the exchange and by other factors related to the shape of the set.

At present there are no data clearly demonstrating that the flush effect in vivo is comparable to the combined effects of flush and disinfectant. In fact there are no reports clearly demonstrating that the double bag derived systems with no disinfectant can prevent peritonitis as well as the Perugia system. Some investigators who performed in vitro studies on this topic concluded that the flush is safe, but disinfectant is an additional protection[7].

Our experience in CAPD is based on four year experience with the Oreopoulos set, eight year experience with the Y set with in line disinfectant[27,28] and 3 year experience with the Bieffe L3 double bang derived system. Peritonitis rate was 1 episode every 9 patient months with the Oreopoulos set, it is 1/43 episode/patient months with the long Y set and 1/44 episode/patient months with the short branched Y set. The peritonitis rate in patients treated with the L3 system is 1/21 episode/patient months.

Based on our experience and clinical impressions, we cannot draw any firm conclusion, but we can list the pros and contras of the Y sets we used in these years:

1) Baxter long Y set and Sifra Perugia system: The first step of the exchange is the perforation of the bag in the open air. Performing the exchange is relatively easy. The use of relatively large amounts of in line disinfectant gives a good protection against contaminating bacteria. The flush is effective mostly on the outlet line (two liters), while the inlet line is washed only by small amounts (about 20 ml) of fresh dialysis solution at the beginning of the exchange. This is the less expensive Y system. No retraining is necessary. The risk of symptomatic accidental introduction of disinfectant is high. The risk of asymptomatic introduction of disinfectant is theoretically very low.

2) Short Baxter Y set: Two connections have to be performed during the exchange. A plastic cone has to be broken out, with consequent risk of introduction of plastic particles into the peritoneal cavity. Published studies on this set seem to indicate similar protection from bacteria contamination in the long and short Y system. The initial flush in the inlet branch is smaller than in the long set. There is a partial inactivation of the disinfectant after 8 hour dwell. The risk of symptomatic introduction of disinfectant is lower than that observed with the long set. The risk of asymptomatic introduction is theoretically expect-

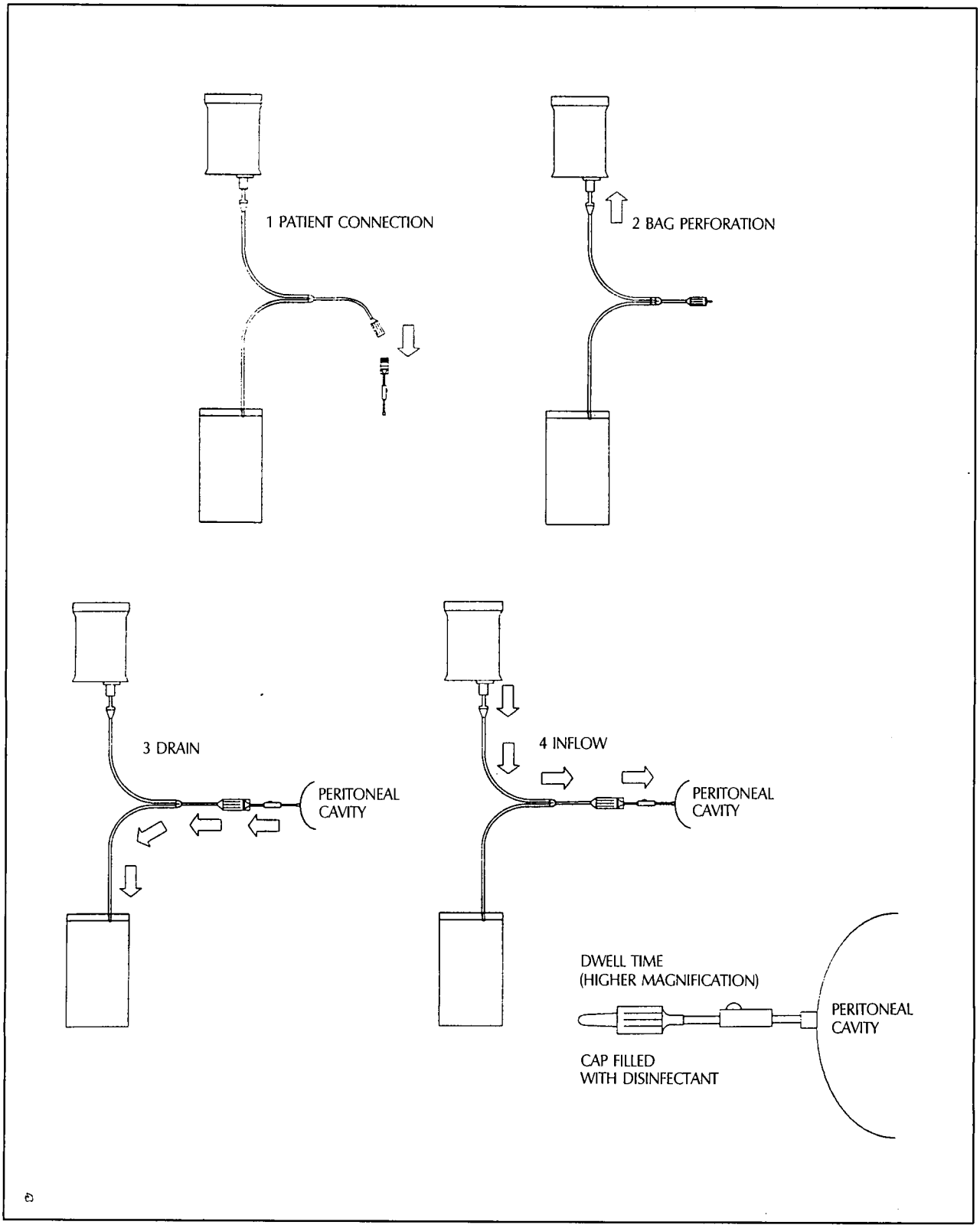

Fig. 6.—Schematic picture of the exchange steps with the L3 system.

ed to be higher. The cost of the short Y set is similar to that of Bieffe L3 double bag system, but the short Y set is more expensive than the long Y set. Performing the exchange is relatively difficult requiring several manouvers. The short Y set is more comfortable and aestethically acceptable than the long Y set but less than the Bieffe L3.

3) Bieffe L3: This system has no frangible cones and a single open connection has to be performed, being the perforation of the bag performed in a closed system. The protection is based on the 2.5 ml of disinfectant (Amuchina, 5,500 ppm of active chloride) contained into the cap of the luer lock (fig. 6), on the 2 liter wash out of the outlet branch and the connecting point and finally on the sterility of the Y set. The disinfectant is largely inactivated after 8 hour dwell. There is no risk of symptomatic accidental introduction of disinfectant with minimal theoretical risk of asymptomatic introduction. The cost is similar to that of the short Y set and is higher than the cost of the long Y set. The L3 is the easiest to be handled and it is as comfortable as the short Y set. Being extremely easy to use, a short retraining after 1-2 years is advisable. Some near sighted, non compliant or low dexterity patients who could not learn to perform the CAPD exchange with the long Y set were rapidly trained to the L3 system.

In 1990 we started a prospective study comparing the incidence of peritonitis in CAPD patients using the Y set with disinfectant or the Bieffe L3 system.

If we had no randomization protocol, our guidelines for the use of these sets should be:

Long Y set: first choice, being theoretically the most protective against bacterial contamination.

L3 system: first choice for young patients with aestethical problems, or for very old patients with low compliance and/or low dexterity, or for near sighted patients.

Acknowledgements:

The author is grateful to prof. C. Ponticelli and dr A. Scalamogna for their useful suggestions for the preparation of this manuscript.

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