Subcutaneous jet injection
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CHAPTER 10

SUMMARIZING DISCUSSION AND FINAL CONCLUSIONS WITH DUTCH TRANSLATION

10.1. SUMMARIZING DISCUSSION

Since the introduction of subcutaneous medicament administration, by Wood in 1853, the technique has become an indispensable tool in our therapeutic arsenal. Every day, hundreds of thousands of injections are given all over the world.

In CHAPTER 1 the possible advantages of jet injection as a method of applying subcutaneous injections are indicated. This needleless technique, in which a minuscule stream of fluid is shot through the intact skin purely as a result of the high pressure, is patient-friendly and economical to use. However, before the technique can be applied in clinical practice, it has to be established whether it is at least equivalent to the conventional needle technique.

In CHAPTER 2 the history of the subcutaneous injection technique is described. Besides the development of the needle and syringe, insights into the systemic action of locally administered medicaments has been essential for the extensive application of subcutaneous injection. Nearly 100 years after the introduction of the needle and syringe for subcutaneous injections, the first commercial jet injector was described by Hingson and Hughes. Since then dozens of jet injectors have appeared, whether or not applied clinically and usually fell into oblivion. Particularly the technical problems associated with these complicated instruments meant that the operational life of most of them was short. Also the unreliability of the volume administered added to their unpopularity. Spilling of the injection fluid was often observed or inadvertent intracutaneous injection occurred.

The most recent development in the field of jet injection is the (only commercially available) gas-driven jet injector, the Med-E-Jet®. This is the most advanced jet injector in present use.

In CHAPTER 3 the technical and practical aspects of the Med-E-Jet® are discussed. It appears that the continuous gas pressure and the possibility to finely adjust a minimum pressure, distinguish it from all the spring-driven versions. Its light weight and the ease with which it can be assembled and disassembled makes it suitable for use within the hospital.

If physicians also wish to use this jet injector for applying medicaments which, for any reason, may only be administered into the subcutis, the injector must be able to supply enough force to guarantee reliable penetration. The characteristics of the underlying penetration layer, for example the skin, play a part but it will be obvious that there is a minimum pressure, below which penetration of the skin cannot be guaranteed. In order to investigate the relationship between this pressure and the penetration depth in tissue, it is necessary to be able to measure the jet pressure.

In CHAPTER 4 a description is given of how, by means of laboratory experiments, jet pressure can be displayed as a function of time. In this way, it has been established that the jet pressure supplied by a fully
loaded Med-F-Jet® injector is about 500 bar. Moreover, the jet speed can be calculated from the profile of the jet stream. At 500 bar it is approximately 180 m/s. Neither the viscosity of the fluid nor the diameter of the nozzle have any important influence on the level of jet pressure produced. Therefore, many figures on jet speed and pressure, which have been circulating in the literature for many years, have been refuted.

It also appears that if the distance between the nozzle and the skin is increased (up to 30 mm), the jet pressure does not decrease. The diameter of the jet stream does increase owing to its divergent nature, thus the penetration depth in tissue decreases accordingly. This is accompanied by intracutaneous deposition and volume loss at the moment of penetration. A spacer (used to achieve a constant distance between the nozzle and the skin) is employed for intracutaneous vaccinations, but often leads to inaccuracies in the volume injected. But in view of the quick succession with which injections can be given using a jet injector and the cuts in the cost of personnel and material, in situations where a great many injections must be given in a short space of time (e.g. for mass vaccinations), jet injection is still a very popular technique.

In CHAPTER 5 the relationship between jet pressure and penetration in (abdominal wall) tissue has been investigated in the light of the data in Chapter 4. If the nozzle is placed against the skin for the purpose of producing subcutaneous penetration, a minimum jet pressure is necessary. The results have shown that a jet pressure of ±350 bar is required to give a constant, reliable deposition of at least 0.2 ml of fluid in the subcutaneous space, which is comparable to the conventional needle injection technique. From data in the literature it is apparent that many jet injectors were not able to produce this amount of pressure. This is possibly the reason why so many of them dropped out of the picture again.

Besides the penetration depth, which can be adjusted by means of the jet pressure, the distribution of the medicament in the subcutaneous space and the tissue reaction are also of importance.

In CHAPTER 6, the conclusion is drawn on the basis of data from the literature that there is no difference between an injection with a needle or with a jet injector. Both techniques recognize the chance of intravascular injection, the small chance of nerve damage and flushing epithelial cells into the subcutis. Histologically, there is no significant difference between the two techniques and the fear of injecting too deeply into the tissue with a jet injector does not appear to be legitimate in practice.

The distribution of the deposit is determined solely by the structure of the subcutaneous tissue. The fluid follows the path of least resistance, giving rise to irregularly shaped deposits. Serious problems have seldom been described following the use of a jet injector. The most frequently documented problem, superficial laceration of the skin (because the nozzle is not held steadily enough during injection), is a shortcoming in manual skill and can be avoided.

Although in contrast to the needle technique, no part of a jet injector penetrates the body, jet injection should be regarded as an invasive technique in our opinion. The skin barrier is broken at the injection site and local bleeding is more than with subcutaneous injection.

In CHAPTER 7 the historical research and publications stated that the jet injection was a possible future development for example with local anaesthetics. The danger of a possibly small, jet-injected volume of disinfectant is to conduct jet injections on patients without cross-contamination. This is necessary to avoid the risk of cross-contamination with each shot. Local anaesthesia is certainly more likely after jet injection, the influence becomes continuous and is always protected.

From CHAPTER 8 the handling virus techniques are a complex and thorough research involving viral transmission. In one study in which virus was transmitted from a contaminated one-way jet, jet injection, produced deposits which viral transmission from a contaminated one-way jet injection, produced deposits which viral transmission has been made before and after the application of a hepatic protamine, a heparin sulfate from the Florida liverstock. The concept of jet injection has been used in a spread and large-scale unmanned series. Therefore, people currently regarding advanced topics require a series of safety and sterilization. In this chapter, the inspector of
and local bleeding occurs more frequently than with subcutaneous needle injections.

In CHAPTER 7 the results of bacteriological research are described which support publications in the literature, in which it is stated that the chance of bacterial contamination and the subsequent formation of, for example, injection abscesses is negligibly small. Jet injection itself does not have any bactericidal properties. A simple disinfectant protocol is probably sufficient to conduct jet injections on a series of patients without the danger of bacterial cross-contamination and without it being necessary to sterilize the injector after each shot. Daily flushing with 0.1% PVP-Iodine is cheap and takes little time. In the unlikely event that the medicinal head becomes contaminated, it gives adequate protection.

From CHAPTER 8 it is clear that excluding virus transmission with a jet injector is a completely different matter. Thorough research into safety measures regarding viral transmission is lacking. Our own study in which LDH virus was transmitted from a contaminated mouse to an uncontaminated one with the only vehicle being the jet injector, is in fact the first study in which viral transmission with a jet injector has been made plausible. Moreover, just before the appearance of the data in article form, a hepatitis B explosion was reported in Florida following the use of the same type of jet injector, which gave rise to large-scale unrest. From that moment onwards, people have been very reserved regarding advice on the use of a jet injector for series of patients, without interim sterilization. In 1986 in the Netherlands, the inspector of health went as far as banning the use of the jet injector for the above mentioned application. Although based on a once-off animal experiment, in which the nozzle was placed directly on the skin, these data have apparently been extrapolated to intracutaneous vaccinations (in which, in principle, there is no direct contact between the nozzle and the skin). Despite the minuteness of the chance of viral transmission, these findings have rendered the jet injector unsafe for application on series of patients. The use of disposable auxiliary equipment or interim changing of the nozzle, directly counteract the economical and time-saving advantages of jet injection. Furthermore, it will have to be proved that these measures do in fact offer optimal protection in the event of viral contamination. Until that time the jet injector will not be applied for series of patients within Dutch medical practice.

In CHAPTER 9 the pharmacokinetic aspects of medicaments, such as low dose heparin, which have been described, are not of importance at present. Both from data in the literature and on the grounds of our own research, it can be concluded that there is no clinically relevant difference between the resorption process of heparin after jet or needle injection. Through the wider distribution of medicaments after jet injection, it appears that resorption takes place more homogeneously and probably at a faster rate initially than following needle injection. Although the literature on the jet injection of insulin is not univocal, it is advisable to monitor blood glucose levels more frequently in the early stages after jet injection. With reference to the data in Chapters 2 through 9, the following conclusions can be drawn:
The first hypothesis, in which the reliability of the injection method and its harmless for the tissue are the centre of interest, is supported by the results of this study.

There is no essential difference between the administration of medicaments using a needle or a jet injector with regard to the penetration depth, volume and tissue reaction. Therefore, no clinically relevant difference in resorption will be found between the techniques.

On account of the chance of viral transmission demonstrated in this study and supported by a hepatitis explosion, the second hypothesis must be refuted. For the time being, the jet injection technique for the subcutaneous administration of medicaments is not without risk, which means that its use on series of patients is presently not permitted in the Netherlands. Injections of tetanus toxin and low dose heparin have therefore been dropped as fields of indication. The individual use of a jet injector for diabetic patients who require insulin injections has been retained. It is interesting to note that, forty years ago, the first patient to be injected with a jet gun was a diabetic patient. Also incidental use, with interim sterilization, is still possible. However, the economic advantages of wide-scale use in clinical practice are cancelled out in this way.

It therefore appears that the formerly very promising, highly propagated injection technique has not (yet) managed to gain a place alongside the conventional needle technique.

In view of the many valuable advantages offered by jet injection, it is important that further research be conducted in an attempt to bring this technique to perfection.

The problem of viral transmission will probably be solved in the future, so that the jet injector will ultimately gain the, in our opinion, well-deserved place within the arsenal of parenteral administration forms of medication.

10.2. FINAL CONCLUSIONS

The use of a Med-E-Jet® injector to deposit medicaments into the subcutaneous space is a technique which does not display any clinically relevant difference compared to conventional needle injection. In view of its patient-friendly character, it should actually be the preferred technique. The economic advantages of using a jet injector on series of patients are counteracted by the fact that it appears to be possible for viral infections to be transmitted with a jet injector from one patient to another.

Until a solution has been found to this problem, the application of jet injection will remain restricted to individual use or the equipment will have to be sterilized between patients.

10.3. REFERENCES

1. Leads from the MMWR. Hepatitis B associated with jet gun injection-California. JAMA 1986:256:446-7

10.4. DUTCH SUMMARY

De subcutane toepassing van medicamenteus is een techniek die de therapeutische effecten van de naald met het voordeel dat deze niet wordt ingeschopt. De naald is dan ook niet meer noodzakelijk.

In HOOFDSTUK 3 is de ontwikkeling van de subcutane toepassing van medicamenteus beschreven. Bijna honderd jaar geleden werd de eerste inenting door de naald gedaan. Dit bleek onmogelijk. Later door Hingswood en de naald werd de eerste inenting bij een hond door Hingswood. De subcutane toepassing van medicamenteus is echter voldoende erkenning gevonden. De techniek is echter voldoende erkenning gevonden die de techniek niet zonder risico is.

In HOOFDSTUK 4 is de toepassing van medicamenteus in de praktijk besproken. Het aanvoeren van medicamenteus via de naald is niet zonder risico. De subcutane toepassing van medicamenteus is echter voldoende erkenning gevonden. De techniek is echter voldoende erkenning gevonden die de techniek niet zonder risico is.