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Moderator

Trine Grönlund



Founder of
Innergi-Labbet



Dermatology experts roundtable

Benefits and challenges
of dermatologicals in the
management of skin
disorders



31st EUROPEAN VETERINARY
DERMATOLOGY CONGRESS
ORGANIZED BY ESVD-ECVD
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DOUXO^{S3} & antibiotic reduction

Moderator TG We should start with a very topical issue: the need to reduce the use of antibiotics, which should be used as little as possible and only if absolutely necessary. We all know this is critical both in human and in veterinary medicine. Tim and Chiara, you have both been part of the GRAM project, the Guidance for the Rational use of AntiMicrobials. Tim, what would you say is the overall attitude towards non-drug solutions such as dermatopicals versus antibiotics in veterinary practice?

› TN We all recognise that we need to use fewer antibiotics. Studies have shown that topical chlorhexidine-containing products have been at least as effective as systemic antimicrobials. However, their disadvantage is it's more effort for the owner. So having products permitting to apply one shampoo and then only mousse over three weeks makes a huge difference in terms of compliance. The results are excellent. I have to admit, I told Ceva the single-shampoo protocol

wouldn't work. I'm very impressed with the results and I think they can make a huge difference to antimicrobial stewardship.

› CN These topical products containing chlorhexidine can kill bacteria whether they are sensitive or resistant to antibiotics. So they actually do a good job, much better than antibiotics because antibiotics will not kill the bacteria that are resistant to them. So they're not just equivalent, they maybe even better.

› TN Studies have shown that for amoxicillin – clavulanic – susceptible *Staphylococcus pseudintermedius* the efficacy is equivalent, but it can also be effective against things like MRSP. So I totally agree.

› CN That's important and it also saves money because you don't have to do a bacterial culture and susceptibility test.

› TN And it also saves the need of higher-tier, non-licensed antibiotics

that really should be reserved for the critical cases or for use in humans only.

› RM Somebody in the audience said "we've done that for years, topical treatment". We all did it for years. I think what's new here is not that we use a shampoo to combat bacteria – anybody who starts now is a little late – but it's the effect we get, using a mousse as a maintenance. And that is something! Tim and I at least have used mousses for years, too. But to my knowledge that hasn't really been shown in a nice study as we saw here [with the DOUXO^{S3} innovative protocol], that this really works as well as I actually had anticipated it. What's special about this is that we can now, for short-coated dogs and owners that don't like the shampooing because it's cold outside, because it's a Newfoundland and doesn't want to go in the bathtub or whatever... that you can, with more localised disease, use a mousse instead. That's something that is really valuable.

S³ – SAFE SKINCARE SELECTION & Ophytrium's selection



« These skin models are great because they are a very good early way of screening for efficacy on all sorts of different levels but without using animal models.

It's fantastic, it's been able to provide evidence without experimenting on animals. »

– Dr. Tim Nuttall

We've heard about this unique and very demanding process that Ceva has been through to arrive at DOUXO^{S3} and Ophytrium as the governing ingredient. I'm curious to hear what you think of the process and the number of studies, the quality of the studies.

› MCC There are numerous studies and they developed this new range of products, a bit like they would have developed a drug. And that's something which is really impressive. That's why today there are so many studies to discover and present. I think it's a great thing.

› TN I agree. It's beginning to set the bar to the level of evidence of what we expect to see with a new topical product so that we can have confidence in it. In the past, we've all seen topical products that have been marketed with very little evidence to support their use, and we haven't been able to replicate that in clinical practice.

What is your opinion on the whole skin model used in the research process?

› TN I think it is fantastic. These skin models are great because they are a very good early way of screening for efficacy on all sorts of different levels but without using animal models. It's fantastic, it's been able to provide evidence without experimenting on animals.

› CN ...and cell toxicity and safety.

› RM Having said that, I appreciate it for the safety and everything, but I would like clinical studies nevertheless, to confirm.

› CN Absolutely, yes.

› MCC It's a first step and it needs to be confirmed later. But on the other hand, starting from scratch on animals with clinical studies – which are difficult; recruiting those cases takes time and it's hard – so I think it's a good thing.

› RM And you have a much lower likelihood that you then have a bad surprise.

Regarding the Ophytrium that was selected, is it unusual to have that package of data when it comes to an ingredient in dermatopicals both in terms of what we now have on performance and safety?

› VB Yes. I think it is very rare for a product that is not a drug to have this type of selection, this type of studies, with a lot of information about toxicology, about cytology,

about efficacy. I think the product is important but the development of the process is perhaps the most beautiful thing here today.

› MCC I could add that it's important to know about the active ingredient but also doing these preliminary studies brings new data. It's important for science and for knowledge. So in addition to studying an active ingredient – or lots of active ingredients – it also helps the veterinary field in another way, and I think that's important.

Benefits in atopic dogs

The same extract than Ophytrium was tested on atopic people which led to an improvement of the quality of life for the patients. Ralf, what would you say about the benefits of topicals in the management of atopic dermatitis in pets?

› RM It's something that we have done a lot. But what's new with these products is that we have a little bit more data confirming that it actually does what we think it does. And in a lot of atopic dogs – particularly those that have localised disease, feet or belly only or stuff like that - the topicals that we used to use twenty years ago were overwhelmingly shampoos. And a lot of owners – at least in my clinic – go “oh no, now I have to shampoo him again and he hates it. And I have to lift him in the bathtub and lift him out again...” It's a huge effort

and with the mousse it's all suddenly much easier. And so the compliance is higher and so the success is higher. You will find differences in the results, specifically with topicals, if you don't do it on a regular basis. I think it's great.

› CN Could I say a small word about compliance in cats? I love cats, you all know I love cats. And having a mousse is different from having a spray and is certainly different from having a shampoo. So the formulation is a big, big plus.

What kind of signal does it send to the users, the fact that it actually has been used and tested on people?

› RM They're happy; “it must be safe”. If it was ‘experimented on’ in humans, then it ‘must be OK for the pets’. So the bar is of course set at a certain level.



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– Pr. Ralf Müller



Pet owners & product safety

We talked a lot about the fact that this product has been developed in close proximity with the end users and with the vets. One of the concerns that pet owners very often raise is the concern of safety. Overall, they want to be able to trust the brand, they want to be able to feel confident that there are no controversial ingredients in the products, they want to make sure that it's safe to use, both on their pet and for themselves. Are you facing these concerns Susanne?

› SA This is an issue we have on a daily basis. We have owners – I'm sure you also have them – that are super concerned about anything they expose their pet to. They're super concerned about the food; they're super concerned about any topical products or any drug we prescribe. They will read the backside of any food label or shampoo label. I felt very comfortable in saying there's good safety documentation, good

safety data on the use of these, and I feel comfortable in recommending it. It is a big issue, for at least a lot of my owners – and a part that I thought was very good.

- › PMC During the in-field trials we had excellent results on tolerance, people were very reassured about that.
- › CN Not only safe for the dog, but also safe for the person that is actually applying the shampoo and rubbing in the mousse. Because they also have skin and we don't think about that too much, so this is also a very important issue.
- › SA A lot of the owners, when they use a topical product – topical steroids, topical tacrolimus or topical shampoos – they never think about themselves. You really have to emphasise that: “use gloves”, “rinse your skin” or “report if you get red skin on your own hands – please report it and we'll swap the type of treatment”. So it's really an important issue.



« We have owners [...] that are super concerned about anything they expose their pet to.

[...] I felt very comfortable in saying there's good safety documentation, good safety data on the use of [DOUXO S3], and I feel comfortable in recommending it»

– Dr. Susanne Åhman

Compliance



« [In cats,] having a mousse is different from having a spray and is certainly different from having a shampoo. So the formulation is a big, big plus.»

– Dr. Chiara Noli



« During the in-field trial the owners reported that what is important to them is a good fragrance, a nice texture and a product easy to apply. The satisfaction to use the product is good for observance and a better way to help dogs improve.»

– Dr. Pierre-Marie Cadot

So we've certainly highlighted some of the benefits today. I'd like to talk a bit about the challenges. Compliance is a really critical topic and efficacy is given, so we expect that. What else is there we can do to increase compliance? Do you have any feedback from the field that you can share?

› RM There's an English saying 'Horses for courses'. It's important to choose the right product for the right animal. There are some owners that love to shampoo and they don't like a mousse. And then the protocol of one shampooing and then the mousse 3 times weekly will not lead to compliance because they don't like it. There are others where it's the other way around: they hate shampooing for the reasons that we have mentioned already. And then you have an alternative: you don't have to shampoo; you can do it just once or we do it in the clinic and then we send your dog home and you do the mousse. So you have more options now with this. You just have to look at the owner and

then of course the dog. With a Chow-chow with generalised skin disease, I would not use a mousse – because I don't think you're going to get where you want to go. But if you have a Boxer with just a belly itch, there's nothing better than a mousse. So you have to look at it case by case.

- › SA With compliance you also need to adjust the treatment to the owner. Another detail that might sound ridiculous is the shape of the bottle.

Feedback from a lot of the owners, the majority of the ones I recruited gave feedback saying they wanted to hold the shampoo bottle with one hand, keep the dog in the shower with the other hand; therefore they were able to go through with the shampoo without having a wet dog running around the house. This is something I would not really have considered – the questions would have been on the protocol – but if you're looking

at compliance, that is actually a factor that, from a scientific point of view, doesn't really matter but from a practical point of view, will matter.

- › PMC and during the in-field trial the owners reported that what is important to them is a good fragrance, a nice texture and a product easy to apply. The satisfaction to use the product is good for observance and a better way to help dogs improve.



« The majority of the ones I recruited gave feedback saying they wanted to hold the shampoo bottle with one hand, keep the dog in the shower with the other hand; therefore they were able to go through with the shampoo without having a wet dog running around the house. This is something I would not really have considered [...] but if you're looking at compliance, that is actually a factor that, [...] from a practical point of view, will matter. »

– Dr. Susanne Åhman



Refill bottles

Audience Very interesting to hear about the shape of the bottle. I'm married to a product designer so he would have loved it. Have you considered using refillable pouches for the shampoo, from an environmental perspective? I think that would

increase the compliance with a lot of my customers.

- › M. Rougier, Ceva Yes of course we've considered that. For the moment, the data that we have is that we don't have many pet owners that are re-using the shampoo

bottles in the long-term. A lot of evidence is they only use it during the flares. But of course we're investing to look at that. It's a pump so you can open it and refill it. So it's one of the evolutions that we want for the future.

Control studies

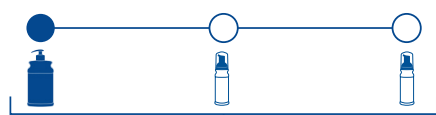
Audience Interesting studies, but don't you miss the controls? At least you should mention you don't have a control. You don't know what would happen if just washing with water. And we consider this as a 'kind of drug' – what would be required for registration? It would be to compare it with something we have on the market, or the base, as control. It's really an issue. Is it in the pipeline for the company to have a comparative study?

- › M. Rougier, Ceva Yes, we're still investing a lot in those products. We currently have other clinical studies and we have included some with a control group. We hope to be able to present you more information in the future.

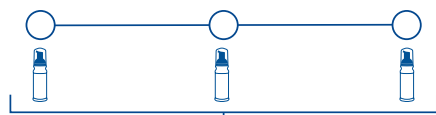


DOUXO^{S3} innovative protocol

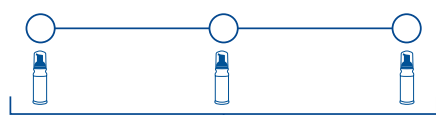
Innovative DOUXO[®] S3 protocol



1st week



2nd week



3rd week



Only 1 Shampoo
to clean the fur and skin



Mousse 3 times a week
for performance

Moderator TG *We talked about the importance of the fragrance and of the packaging and how it affects usage. It is crucial to help the pet owners treat their animals without any compromise on the performance. Now we have this new protocol – with only one shampoo and then mousse –. Ralf, what is your overall experience with the leave-on mousse and galenic?*

› RM “It depends” is the right answer. I think with the galenic – or with how the dogs take it – I have very good experience, that works really well. But compliance depends mostly on the owner, and there it's much more subjective. I make my individual protocols really very much suited to owner and pet, as a combination. That's why I like having both. In some, I don't use the mousse at all. In others I decide not to use the shampoo. And in others I combine. I'm very creative!

› TN I'm the same. A long-coated, very heavy double-coated dog... it was a struggle and I did have some owners who said they needed more than the instructed number of pumps per kg of dog to work it in. It depends on the owner of the dog that's affected as well. I have dogs that are phobic of showers so I think the idea of giving the owners the flexibility of putting it on, in a busy household without having to go into the shower, without having to fight with the dog, without having to rinse it and dry it... most of my owners really appreciated that.

› VB Perhaps with this today it is now possible to have an efficient result with mostly mousse. So we have a choice between doing a shampoo or mousse. And perhaps it is the beginning of a way to a customisation of treatment, to have the choice between different treatments and different protocols.

Audience *Have you used the mousse on pododermatitis? How easy was it?*

› RM It depends, like with many other body sites. Some dogs have almost no hair interdigitally, and then it's very easy. I usually tell the owner that they must prevent licking for the first couple of minutes, then you don't have to worry. Then we have dogs that are really densely coated, and some of the Chow-chows or Akitas or Huskies, they have so much hair in-between the toes that it is harder. So again, it depends on the patient.

› TN Also, if you've got a nice open interdigital web, then the mousse is fine. But if you've got chronic change and folding and build-up of seborrhoea, desquamated material and grit getting into those folds, then some form of active cleaning is required. You could use a mousse plus a tissue or wipe, but I think a shampoo is probably going to be more effective. Or a soap. But I still think you actually need to get in and remove that foreign material.



Seborrhea and smelly dogs

Moderator TG *Marie-Christine, I was thinking about the whole notion of a smelly dog and you feel that you're doing something but nothing happens. What is your experience with the topical products?*

› MCC I've mostly worked on DOUXO[®] S3 SEB and like Tim, I told Ceva that one shampoo and the rest of the protocol with mousse wouldn't work – sorry, I was wrong! I was really impressed

by the mousse. And also because I had the experience with dogs coming in for a re-check and being wet. So supposedly not really with a great 'odour'. And having had the mousse a few days before, they had the nice fragrance of the mousse, not at all the bad smelly wet-dog odour, and I was really impressed. And I wasn't the only one to notice. The owners said, look, it now smells nice!



« I was really impressed by the mousse. [...] they had the nice fragrance of the mousse, not at all the bad smelly wet-dog odour, and I was really impressed. And I wasn't the only one to notice. The owners said, look, it now smells nice! »

– Dr. Marie-Christine Cadiergues

Owner satisfaction



Overall, in what way do you think that the whole launch of DOUXO® S3 will help you in your practice and help your clients, the pet owners and the pets? Can you give us a last round of thoughts on that?

- › PMC During the in-field trials, I was impressed by the satisfaction of the clients. And at the end, some of the pet owners wanted to buy the product. I said “I can’t, it’s impossible” and they were not happy and that was a problem. And they wanted to keep all the products and I told them I had to give them back to Ceva and they were not happy with that. So we have a new solution.
- › SA I was mainly involved in the CALM and SEB protocol. Especially in the

CALM protocol, the owners were really, really happy. This product has a higher concentration of Ophthirium, I don’t know if that is an issue because previously I hadn’t been so impressed with the shampoos that are meant to just reduce pruritus. I’ve used a lot of chlorhexidine shampoos but I haven’t been so impressed with the ones that are just meant to reduce the pruritus. I think the experience with the CALM product actually made a difference for dogs that I had to deal with. I think that is promising.

- › VB I don’t have anything to add. Yes it’s true. Owner satisfaction was really good. And the satisfaction of the vets (us!) was also good. I have no doubt that it will also be satisfactory to other clients.

Breakthrough innovation

We talked that this is a breakthrough innovation when it comes to topical products for skin. Do you think that this is a breakthrough, that this could change the way that we manage skin disorders?

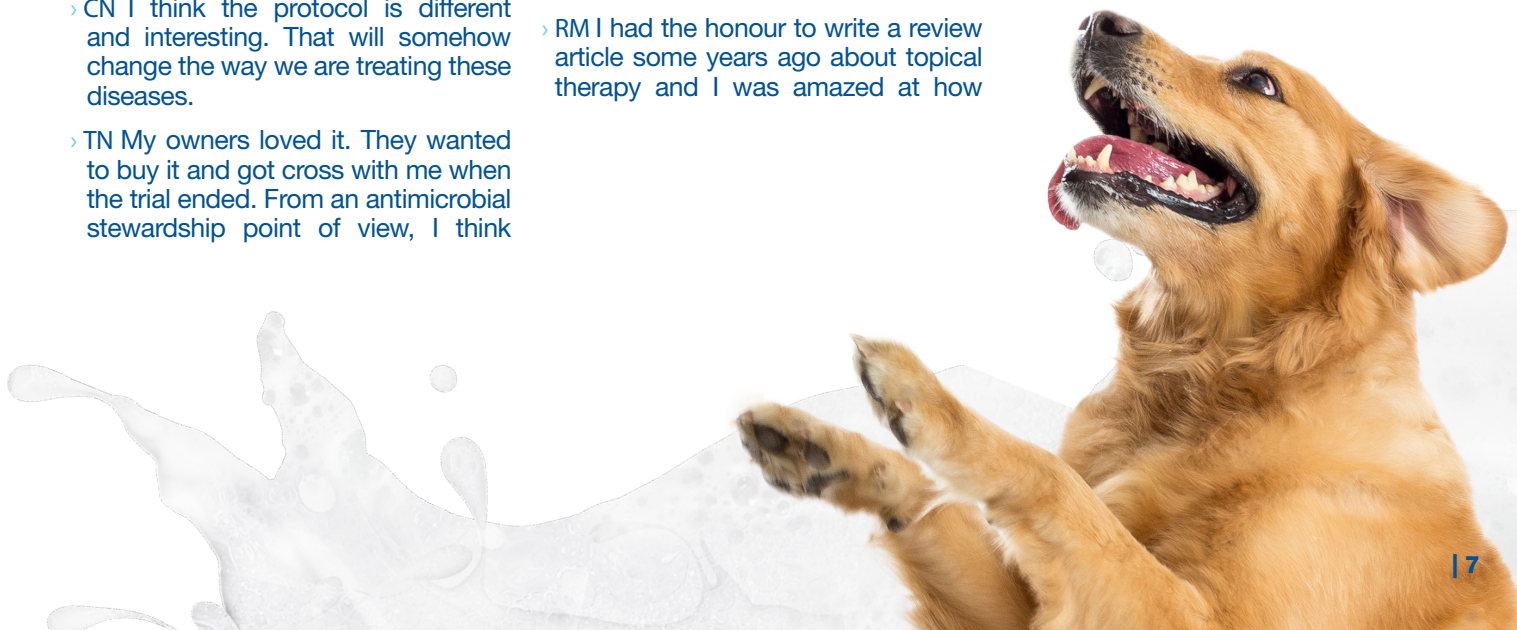
- › RM I’m going to disappoint you, but no- I don’t think this will change my way to use these. Because the products that we had before, were not that bad either. I’ve been using a lot of the DOUXO®, mousse + shampoo, before. But I think it’s going to be better than the old ones. And I think the satisfaction will be a little higher and so I look forward to be able to use it on more patients than just the study patients.
- › CN I think the protocol is different and interesting. That will somehow change the way we are treating these diseases.
- › TN My owners loved it. They wanted to buy it and got cross with me when the trial ended. From an antimicrobial stewardship point of view, I think

perhaps this is a breakthrough because that one shampoo and then three weeks of mousse was equally effective as a more intensive bathing protocol, which I think is a reasonable control given the known efficacy of these products. I think that could make a big difference to compliance and for reducing systemic antibiotic use. I take the point that there weren’t any control studies in the CALM and SEB protocols, which is being looked at. When we look at other topical products, sometimes there is no evidence beyond claim to efficacy and claim to safety, so I think that this is a strong move in the right direction towards greater evidence-based medicine in topical therapy.

- › RM I had the honour to write a review article some years ago about topical therapy and I was amazed at how

little in-vivo data was available with any of the products that were on the market. So I think it’s really good that we have data on this one.

- › MCC I fully agree. Having said that, I think there are some things that won’t change; we still need to educate the owners – and the vets. And also, we need not believe that just because a product is great it will be applied for a long term. We need to follow the cases, and recheck again and again and repeat the messages – even if the products are better, even if there is more flexibility. So yes, they are better – they are great – but the dogs are not doing the jobs themselves!



Take Home Messages

Moderator I would like to send everyone home with just one sentence, a catchy sentence. If they should just remember one thing today what should it be?

- TN I think the big take-home message is **the science and the safety, and the fact that topical therapy can make a difference...** I keep banging on antimicrobial stewardship, those people who know me know that that's very important to me. But also, this could be the difference between a dog having to stay on oclacitinib every 12 hours and being able to go to every 24 h, or being able to maintain on a topical plus immunotherapy. So it's not a magic cure but it can be a very significant adjunct. And again, **this mousse protocol makes it so much easier for the client.**
- RM I just say: **"Go moussing!"**
- VB The name is S3 for SAFE SKINCARE SELECTION, but it could also be S for **strength of the development process**, S for **simplification of the composition** and also S for **simplicity of the protocol.**
- SA I think that **Ophytrium** may be a **very helpful addition** to the multi-modal therapy for our atopic dogs.
- PMC ...and maybe S4, for **satisfaction of clients.**
- MCC Just to underline that **Ceva is an experienced company for shampoos.** It's not their first range of shampoos, but they made the choice to **improve their own range** and I think it's important to emphasize.
- CN I hope we've presented **the data** and convinced you about this shampoo protocol and I think now you should try it yourself on your dogs and in your practice and you'll see that **it really works.**