

# Study vindicates dual treatment regimen

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A combination of oral and nasal steroids can significantly improve the treatment of chronic rhinosinusitis - a common and often debilitating form of sinusitis - and help avoid surgery, according to new research carried out at the University of Dundee.

Chronic rhinosinusitis affects millions of people in the western world, with almost 15 per cent of the European population estimated to suffer from the disease.

This dual approach, which the study's Principal Investigator likened to mowing the lawn before applying weed killer, demonstrates that steroid pills followed by steroid drops and sprays can safely be used to treat CRN patients who present with nasal polyps.

The study, led by Professor Brian Lipworth from Dundee's Asthma and Allergy Research Group, worked with 60 adults who were referred for evaluation and treatment of CRN, a condition in which inflammation of the lining of the nose and sinuses causes nasal congestion, pressure, pain in the face, and loss of smell.

In some patients, repeated episodes of inflammation due to infections, allergies or other reasons cause the lining of the sinuses to swell up into bags of fluid called polyps, which protrude into the nasal passages and make the condition worse.

Nasal steroid sprays are commonly used to treat CRN, but are ineffective if medium to large polyps are present. Many patients

eventually undergo keyhole-type surgery to remove the polyps and improve sinus drainage.

The study participants were randomly assigned to receive either steroid or placebo pills by mouth for an initial two week period. Both groups were then given steroid drops for two months and then steroid spray for a further of 26 weeks. The researchers measured the size of the polyps in the participants' noses before and after treatment, and asked them about symptoms, such as sense of smell.

The resulting paper, published in the *Annals of Internal Medicine* journal, shows that participants who started out receiving the steroid pills had greater shrinkage of nasal polyps than those who received placebo pills, with these effects being sustained at the end of 28 weeks. In addition, those who received the steroid pills had a greater improvement in their sense of smell. No problematic side effects were seen.

Professor Lipworth said that the findings vindicated a regimen followed in the Rhinology Mega-clinic at Ninewells Hospital in recent years, which had successfully treated CRN patients with polyps, and which had reduced the instances of surgery.

'The principal problem with nasal polyps is that the plumbing of the sinuses is jammed,' he explained. 'Merely taking nasal steroid sprays will not unblock this if you have medium to large polyps. An initial short course of oral steroids under supervision may help the nasal sprays to better penetrate into the sinus openings - and this is what we have now proved in our study.'

'To give a crude analogy, the initial 'mowing of the lawn' with the oral steroid tablets is needed before the 'weed killers', the nasal steroids, are sprayed. Oral steroids produce better access into the sinus cavities for the steroid drops and sprays therefore promoting improved drainage.'

This can act as a 'medical polypectomy' and prevent unnecessary surgery - a regimen which we call 'Dundee Polyp Clear'.

'This is something we have seen in our centre with a reduction in the number of endoscopic surgeries. Moreover, patients are amazed that they can smell again, something that nasal sprays can't achieve on their own.

'Being the principal research centre for rhinosinusitis and asthma in Scotland we routinely conduct community based workshops with primary care physicians and the culture of initial oral steroid treatment for patients with medium to large size polyps is catching on as they observe the significant improvement compared to merely giving nasal steroids.

'Ours is the first study to show not only that it is effective but also that it is safe, especially as almost half of our patients also were taking inhaled steroids for asthma. The oral and nasal steroids did not cause any side effects or lasting detectable adverse effects in the body. Surgery is non-curative and a temporary treatment to open sinus drainage. This can easily be achieved in most people with oral steroids.'

Sense of smell is regarded as a good indicator of the severity of the disease. If this is lost then the study found that, without the initial steroid tablets, most patients relapse quickly.

Professor Lipworth said his clinic now never treats any significant polyp disease without an initial trial course of oral steroids. The evaluation of patients with polyps is approached holistically, with an assessment and treatment of any allergies or asthma. Careful ongoing evaluation and follow up are also necessary.

He said his team was fortunate in that there is a one-stop mega-clinic in

Dundee that allows surgical specialist colleagues to make a joint decision about the need for optimal therapy. This set up serves patients extremely well as they previously tended to be referred back and forth between medical and surgical specialist clinics

The participants in the study were evaluated by specially trained ear, nose, and throat physicians who were expert in recognising nasal polyps. As such, Professor Lipworth said that larger, community-based studies are needed to evaluate efficacy and safety in patients with milder disease.

Not all patients with CRN have nasal polyps. Whether the treatment used in this study would be beneficial in patients who have not been evaluated by specialist physicians, or who do not have nasal polyps, is unknown at the moment.

'We believe that further studies are necessary,' he said. 'This would allow us to look at longer periods of treatment with the steroid nasal drops before switching to nasal sprays.

'Other possibilities would be to look at pulsed therapy with shorter bursts of oral steroid tablets to help maintain shrinkage of polyps as well as looking at other anti-allergy treatments, such as anti-allergy tablets and sprays, to facilitate using a lower dose of steroid.'

Provided by University of Dundee

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