The effect of a stabilised oil (Lyprinol®) from green lipped mussel (Perna canaliculus) on pain and Activities of Daily Life in patients with osteoarthritis in knee and/or hip.
A Pilot investigation.

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Second to heart disease osteoarthritis is the most frequent cause of chronic disablement. Osteoarthritis causes symptoms in approximately 10% of the population in the age group 25-74 years. After the age of 65 around 6% of all people have radiologically proven osteoathritis in the knees, and in Denmark about 4,000 are each year operated for osteoarthritis in the hip.

At the same time the medical treatment of osteoarthritis is far from ideal. NSAID products cause serious damage in the mucus membrane of the stomach and NSAID's are suspected to cause damage to the articular cartilage taken continuously.

In the popular tradition in New Zealand the greenlipped mussel (Perna canaliculus), which lives in the sea outside New Zealand, has a reputation as an effective remedy against arthritis. However, a series of investigations since the 1970's of the effect of dried mussel powder against arthritis, gave conflicting results.

In 1986 researchers succeeded in stabilising the oxygen sensitive parts of the mussel. The oil extracted from this stabilised preparation is further stabilised with olive oil and vitamin E and sold under the trade name Lyprinol(r) (2).

In 1997 T.A. Macrides et al showed that Lyprinol(r) markedly diminished the production of Leukotriene B4 (LTB4) in neutrophil granulocytes. This effect was ascribed to some structurally related 3-fatty acids, among which 3-tetraenoic acid, which is identical to arachidonic acid except for the position of double bonds (I).

Whitehouse et al have demonstated pronounced antinflammatory efficacy in trials with rats with artificially induced chronic polyarthritis resp. autoimmune arthritis. After 16 days of pretreatment the prophylactic effect of 20 mg Lyprinol/kg rat exceeded the effect of 25 m/kg of naproxen. In comparison concentrated fish oils (i.e. Pikasol, Max-EPA) in doses of 1850 mg fish oil/kg rat, had none or negligible effect. Similarly the same dose of Lyprinol was therapeutically clearly superior to 40mg/kg Ibuprofen, while other marine oils had no effect (2)

PATIENTS AND METHODS

Based on the above mentioned results an open pilot investigation was done on out patients with osteoarthritis in the setting of a private clinic. 13 patients with longstanding osteoarthritis in one or both knees and/or hips were included.

Criterias for inclusion in the trial were the presence of pain as well as osteoarthritis proven radiologically and/or with arthroscopy. Patients with concomitant other kinds of arthritis were not included. Median duration of known osteoarthritis were 4.5 years (2-8). 8 women and 5 men aged 35-79 (median 56 years) participated.

Patients were treated with Lyprinol capsules of 150 mg, 2 capsules twice daily the first 25 days, thereafter 1 capsule twice daily. All patients were evaluated before beginning of the trial and subsequently at two control sessions with intervals of 3-4 weeks. Evaluation included - in addition to a global physician assesment - the patients' subjective statement of pain level (on a scale from 0 to 10) as well as the score in a recognised weighted questionary concerning Activities of Daily Life (ADL) (3) - see appendix.

During the investigation it was aimed not to change any existing pain relieving medication.

RESULTS

Two patients did not show up at the second control (table 1). Both of these experienced a worsening of their condition and later resumed treatment on their own initiative outside the pilot trial.

12 of the 13 patients reported less pain at the first control 3-4 weeks after commencement of treatment (table 1, fig. 1). Median reduction in pain score were 3, which is equivalent to a reduction of more than 50% in subjective pain experience (initial median value 5). This result was maintained at the second control (table 1).

Similar results were obtained concerning ADL-score (table 2, fig.2) Only one of the 11 patients (9), who completed the trial, did not experience any improvement in ADL.

One patient (2) experienced initially worsening of the pain during the first two weeks. Apart from this no side effects were seen.

As agreed. none of the patients increased use of painkilling medication, but one did reduce the use as a result of less pain.

Table 1.
SUBJECTIVE EVALUATION OF PAIN.

PATIENT	BEFORE TREATMENT	1. CONTROL	2. CONTROL
1	3	2	1
2	3	2	1
3	8	5	4
4	5	3	3
5	5	4	4
6	4	2	n.a
7	8	4	2
8	3	0	0
9	5	2	5
10	8	1	1
11	7	5	3
12	6	6	n.a
13	2	0	0

Table 2.
PATIENTS EVALUATION OF ADL.

PATIENT	BEFORE TREATMENT	1. CONTROL	2. CONTROL
1	5	4	2
2	7	5	4
3	18	15	16
4	16	12	11
5	13	12	9
6	11	11	n.a.
7	13	5	5
8	5	1	0
9	11	10	12
10	15	6	6
11	9	7	4
12	18	18	n.a.
13	8	0	1

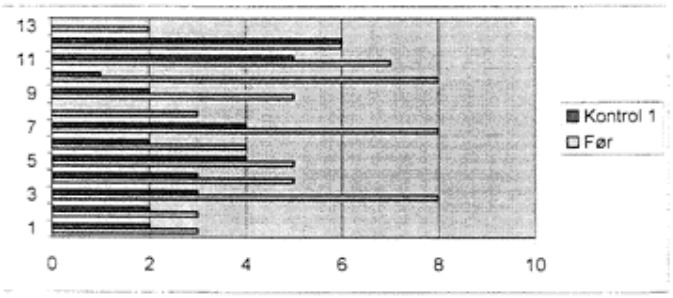

Fig I Pain score initially (For) and after 3-4 weeks of treatment with Lyprinol 2 caps. twice daily (Kontrol 1)

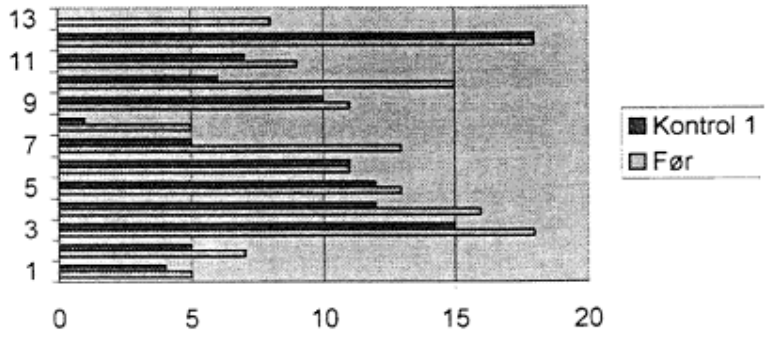

Fig 2 ADL-score initially (For) and after 3-4 weeks of treatment with Lyprinol 2 caps tw ice daily (Kontrol I

DISCUSSION

Of course these results have to be interpreted with reservation, this study being an informal, unblinded and not placebo controlled study. However, it is remarkable, that the effect remained unchanged during further treatment with half the initial dosage for almost one month.

If the achieved reduction in pain and the improvement in ADL can be reproduced in a larger, randomised trial, Lyprinol would seem to be an exceedingly potent drug against pain from osteoarthritis. The achieved reduction of pain of more than 50% should be compared to the reduction of app. 20-30% usually seen with NSAID-preparations (4) On top of this the apparent lack of side effects of Lyprinol is in striking contrast to the frequent and potentially serious side effects seen with NSAID products.

As expected the pain relief was accompanied by a considerable improvement in functional ability as expressed during the ADL-score.

Absence of gastrointestinal symptoms during the treatment corresponds to results on trials with rats, where no gastric problems have occurred even with very high doses of Lyprinol (300 mg/kg rat).

Based on the supposed mechanism of action Lyprinol might be effective against a number of inflammatory diseases. The result of this open trial certainly encourages to further investigations.

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