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Prospective Study of Percutaneous Ozone Treatment of Cervicobrachial Neuralgia (CBN) Due To Disc Herniation

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ABSTRACT

Introduction: *In case of conservative treatment failure in cervical disc herniation, many surgical procedures are offered. Percutaneous surgery seems to have the best benefits. Ozone discolysis is one of the emerging treatments. However, no standardized procedure for this discolysis is yet available. The purpose of this work was to describe our procedure that we have been practicing since 2016 and to assess its results.*

Methods: *From July 2016 to June 2021, we conducted a prospective study in the neurosurgery department of Yalgado Ouedraogo. All consenting patients with cervical disc herniation and conservative treatment failure who have benefited ozone discolysis were included. These patients were reassessed (VAS and neurological examination) at one week, two weeks, one month, three months.*

Results: *Thirty-four cases were retained, representing 39.5% of cervical disc herniation surgeries. Main indications were disabling cervicobrachial neuralgia (CBN) (88.2%) and hyperalgesia CBN (8.8%). Discolysis concerned 1 (52.9%); 2 (29.4%) and 3 (17.6%) levels. At 1 week, 2 weeks, 1 month and 3 months after discolysis were respectively noted 61.8%; 85.3%; 85.3% and 91.2% asymptomatic patients. Pending conventional surgery, discolysis was performed in 1 case (2.9%) of left C5 root plegia resulting in total recovery. No complications were noted. No complications were noted.*

Conclusion: *Cervical discolysis with ozone had very satisfactory results with certain benefits for the patient and his surgeon. It was a good alternative to surgery in our country where the neurosurgeon is the first and only resort in case of cervical disc herniation with failure of conservative treatment.*

Keywords
Herniated disc, Cervicobrachial neuralgia, Ozone, Surgery, Percutaneous.

Introduction
Cervical disc herniation (CDH) is second only to lumbar disc herniation in terms of frequency but its prognosis is more serious because it threatens the spinal cord. It most often manifests itself as the cervicobrachial neuralgia (CBN). It mainly affects adults in full professional activity with a most often favorable evolution under conservative treatment in 78.8% [1] of cases. Many surgical therapeutic procedures are offered with their advantages and disadvantages: conventional open surgery, minimally invasive surgery (microscopic or endoscopic), percutaneous surgery [2]. Percutaneous surgery appears to have the best benefits when the product used is of little or no harm to the patient [3-5]. Thus the chemiodiscolysis with papain formerly used was abandoned because of its complications [6].

Nowadays, with emerging treatments, we have Intradiscal ozone therapy or discolysis (or chemionucleolysis or nucleolysis) with ozone (or oxygen-ozone=. O2-O3). Indeed, ozone at therapeutic dose having total safety, it is used by a number of specialists to relieve pain. This treatment consists of injecting, according to various protocols, a mixture of oxygen and ozone produced by an electric generator. At present, there is still no standardized for this procedure [4]. The purpose of this work is to describe our procedure and to assess the results of this new practice in our work context.

Method
We conducted a prospective study, run over a period of five years from 1 July 2016 to 30 June 2021 in Yalgado Ouedraogo Teaching Hospital neurosurgery department in Ouagadougou, Burkina Faso.

The study population was made up of patients who had admitted for a common CBN without neurological deficits or with a moderate deficit (paresis with muscle strength ≥3/5 or uni radicular plegia with muscle strength <3/5). Were included in the study, all patients in whom the diagnosis of disc CBN with failure of conservative treatment (drug and physical treatment) had been retained and who benefited from cervical discolysis with ozone after giving their enlightened consent. Were not included any case of common CBN effectively treated conservatively, all cases of non-discal CBN, any case of discal CBN after failure of conservative treatment with appearance of a significant neurological deficit (multi-root plegia with muscular strength < 3/5). Conventional surgery had been proposed to these cases of common CBN with a significant deficit. We therefore recorded 266 cases of common CBN without deficit or with a moderate neurological deficit. Among them 180 were improved by the conservative treatment and in 86 cases, there was a failure of the conservative treatment. Among these cases of failure of the conservative treatment, a conventional discectomy had been performed in 52 patients who presented during the conservative treatment a significant neurological deficit. Percutaneous discolysis with ozone was performed in 34 patients who had disc CBN without neurological deficits or with moderate deficit and with failure of conservative treatment. All these 34 patients were included in our study. These patients had not previously benefited from percutaneous discolysis with ozone because this technique is recent in our country and it is the first study that we are carrying out on this subject. Figure 1 shows the flowchart of common CBN cases supported in our service.

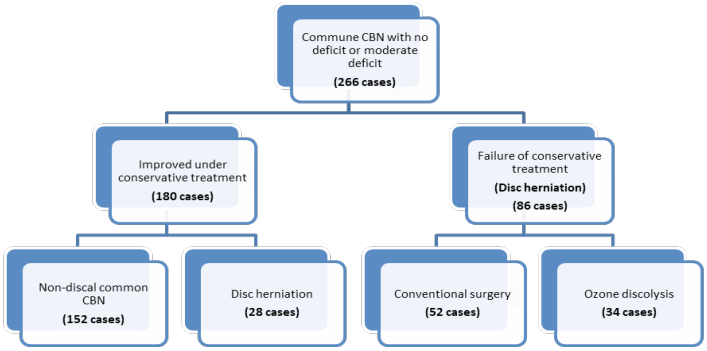

Figure 1: Flowchart of common cervicobrachial neuralgia (CBN) cases managed in the department.

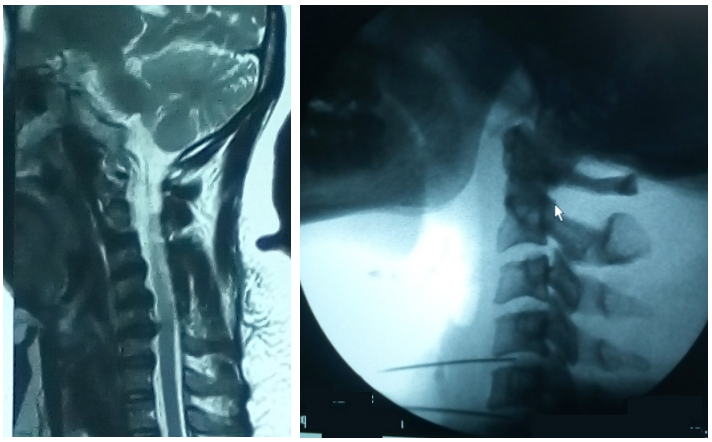

Figure 2: Images of a case of ozone discolysis. **(a)** Pre-procedural MRI T2-weighted sequence and sagittal section showing a C5C6 disc herniation and C4C5 disc protrusion. **(b)** Per procedural fluoroscopy showing the discolysis needle implanted in C4C5 and C5C6.

Concerning percutaneous ozone discolysis procedure; in all patients; discolysis was done on an outpatient basis, under local anesthesia in the operating room with strict compliance with asepsis. Patient is installed in a supine position with blocks under shoulders, the neck in hyperextension and the nose at the zenith; Identification of the disc to be treated with the fluoroscopy, local infiltration of lidocaine sometimes associated with intravenous sedation and analgesia.

We implant a special discolysis needle fine and long in the disc. The cervical entry point was pre sterno scleidomastoid on the side opposite to the maximum pain and then once in the disc, one moves obliquely to the side of the maximum pain. Ozone injection site is at the union of outer third (side of maximum pain), inner two thirds of the disc space on a frontal view and in the middle

of the disc on a profile view. Once the injection site is reached, between 15 and 40 cubic millimeter of an oxygen-ozone mixture (O_2-O_3) is injected whose concentration of ozone in this mixture varies between 15 and 20 micrograms per cubic millimeter. Figure 2 shows images (MRI and procedural per-fluoroscopy) of a case of cervical discolysis.

Thirty minutes to an hour after discolysis patients are allowed to go home. Subsequently, these patients were reassessed on the visual analogic scale (VAS) and neurological at 1 week, 1 weeks, 1 month and 3 months. Thus, there was no pain (VAS = 0 cm). Pain was mild (VAS = 1-2 cm); moderate (VAS = 3-4 cm); intense (VAS = 5-7 cm) or very intense (VAS = 8-10 cm). There was no motor deficit when muscle strength (MS) was rated at 5/5. There was paresis (MS ≥3/5) or plegia (MS < 3/5).

Results

Frequency and Socio-Demographic Data

During the 5-year study period, we performed 34 cases of percutaneous discolysis with ozone. Percutaneous ozone discolysis accounted for 39.5% of disc CBN surgeries with the failure of conservative treatment.

Patients mean age was 48 years with a standard deviation of 12.7 and extremes of 21 years and 75 years. Sex ratio was 3.9 (27 male/7 female).

Diagnostic Data

Average time from the first symptom to first consultation in our department was 23.6 months with extremes of 3 days and 9 years. All patients had received prior drug therapy, of which 16 (47.1%) were parenteral and the remainder enteral. It was paracetamol (34 cases or 100%); nonsteroidal anti-inflammatory drugs (22 cases or 64.7%); corticosteroids (17 cases or 5%); tramadol (16 cases or 47.1%); paracetamol codeine (14 cases or 41.2%); muscle relaxants (7 cases or 20.6%); morphine (3 cases or 8.8%).

No medical history was noted in 28 patients (82.4%). In the other patients, there was arterial hypertension (3 cases or 8.8%); a gastroduodenal ulcer (3 cases or 8.8%); cervical discectomy (1 case or 2.9%). No patients had a history of cervical ozone discolysis.

Functional signs were represented by CBN (20 cases or 58.8%); motor deficit (13 cases or 38.2%); neck pain (3 cases or 8.8%); gait disorders (3 cases or 8.8%); paresthesia of the limbs (2 cases or 5.9%); intermittent claudication (1 case or 2.9%) and constipation (1 case or 2.9%). According to the Visual Analogic Scale (VAS); pain was mild (VAS 1-2) in 16 cases (47.1%); moderate (VAS 3-4) in 2 cases (5.9%); intense (VAS 5-7) in 5 cases (14.7%); very intense (VAS 8-10) in 11 cases (32.4%).

On physical examination, The CBN was systematized following a root traject in 20 patients (58.8%) and not systematized in the others. Neurological examination was normal in 4 patients. Three patients (8.8%) had root motor deficits in upper limbs, including 2 cases of paresis and 1 case of plegia (by left C5 root plegia with muscle strength rated at 1/5). Among them, 02 cases (5.9%) had radicular hypoesthesia in the thoracic limbs and 01 patient (2.9%) had an abolition of right bicipital reflex. Signs of pyramidal irritation (brisk osteotendinous reflexes and/or Hoffman's sign and/or Babinski's sign) were present in 14 patients (41.2%). Thirteen of these patients (38.2%) had paresis. These were 9-tetra paresis, 2 brachial diparesia, 1 paraparesis and 1 hemiparesis.

Ten patients (29.4%) had cervical CT scans and 24 (70.6%) had cervical MRIs. The herniated disc concerned 1 level in 18 cases (52.9%); 2 levels in 10 cases (29.4%) and 3 levels in 6 cases (17.6%). These hernias were C2C3 (1 case or 2.9%); C3C4 (10 cases or 29.4%); C4C5 (21 cases or 61.8%); C5C6 (22 cases or 64.7%); C6C7 (5 cases or 14.7%).

Therapeutic and Evolution Data

Ozone discolysis was indicated after failure of conservative treatment in cases of non-paralyzing CBN (33 cases, i.e., 97.1%) and in 1 case (2.9%) of paralyzing CBN. Among the non-paralyzing CBN, there was disabling CBN in 30 cases or 88.2% (including 17

Table 1: Pre- and post-ozone discolysis VAS, motor deficits and pyramidal irritation signs in patients.

	Pre-discolysis		Post discolysis							
			1 week		2 Weeks		1 month		3 months	
	n	%	n	%	n	%	n	%	n	%
Visual Analogic Scale (VAS)										
No pain (VAS = 0 cm)	0	0.0	21	61.8	29	85.3	29	85.3	31	91.2
Mild pain (VAS = 1-2 cm)	16	47.1	12	35.3	3	8.8	4	11.8	2	5.9
Moderate pain (VAS = 3-4 cm)	2	5.9	1	2.9	2	5.9	1	2.9	1	2.9
Severe pain (VAS = 5-7 cm)	7	20.6	0	0.0	0	0.0	0	0.0	0	0.0
Very severe pain (VAS = 8-10 cm)	9	26.5	0	0.0	0	0.0	0	0.0	0	0.0
Presence of motor deficits and signs of pyramidal irritation	**30**	**88.2**	**25**	**73.5**	**5**	**14.7**	**2**	**5.9**	**0**	**0.0**
Root paresis in thoracic limbs	2	5.9	1	2.9	1	2.9	0	0.0	0	0.0
Root plegia in the thoracic limbs	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0
Pyramidal irritation signs without deficit	14	41.2	13	38.2	4	11.8	2	5.9	0	0.0
Spastic tetra paresis	9	26.5	7	20.6	0	0.0	0	0.0	0	0.0
Spastic brachial diparesis	2	5.9	2	5.9	0	0.0	0	0.0	0	0.0
Spastic paraparesis	1	2.9	1	2.9	0	0.0	0	0.0	0	0.0
Spastic hemiparesis	1	2.9	1	2.9	0	0.0	0	0.0	0	0.0

non-motor deficit and 13 paresis cases) and hyperalgesic CBN in 3 cases (8.8%). The case (2.9%) of paralyzing NCB was represented by left C5 uni radicular plegia with muscle strength rated at 1/5. In the same patient, the number of discs levels treated by discolysis and the site of discolysis were the same as those discs' herniation objectified on medical imaging. We noted no complications related to this procedure.

One week after discolysis, 21 patients (61.8%) reported an absence of pain (VAS= 0); Twelve mild pain (VAS 1-2) and 1 moderate pain (VAS=3-4). At 2 weeks, 29 (85.3%) patients were asymptomatic (absence of pain and deficit). At 1 month, 29 patients (85.3%) were asymptomatic. Three months after discolysis, 31 cases (91.2%) were asymptomatic. Table 1 summarizes the evolution of the VAS, motor deficits and signs of pyramidal irritation of patients.

Discussion

Ozone discolysis accounted for 39.5% of surgical activity for cervicobrachial neuralgia (CBN) by cervical disc herniation with a surgical indication. It was a good alternative to conventional discectomy, especially since this treatment mainly concerned young male subjects (economic lung of our society). Several studies have noted an average age superimposed on ours of 45 years [7], 47 years [8], 48 years [1]. This young age increases the risk of occurrence of post-discectomy recurrences with the corollaries of very laborious surgical revision. In addition, the cost-utility analysis of anterior cervical discectomy and plated fusion (ACDFP) compared to posterior cervical foraminotomy (PCF) in patients with single-level cervical radiculopathy at 1-year follow-up showed that ACDFP was not cost-effective, whereas PCF was [9]. The long-term benefits of these techniques have still been debated (recurrence). Epidural steroid injections (ESI) by an interlaminar approach under fluoroscopic guidance with or without epidural space detection methods have been proposed [10-13]. However, several sometimes-serious complications of interlamaire injections under dural or arachnoid of steroids have been reported: spinal cord injuries, formation of the spinal cord or epidural hematomas, abscesses [10]. On the other hand, no complications or significant side effects were reported during or after the procedure of cervical ozone discolysis [14]. We did not encounter any complications during the procedure or during the follow-up of the cases in our series.

The indication for ozone discolysis in our study was disabling (88.2%), hyperalgic (8.8%) and paralyzing (2.9%) CBN. Diagnosis of herniated disc was most often made on MRI (70.6%). CT scan was performed in only 29.4% of cases. In Morocco [15], the use of CT was low (10%). Indeed, in addition to the clinic, importance of spinal cord/root compression on a CT scan or MRI (size of herniated disc and degree of reduction of the canal) and / or spinal cord suffering on MRI (intramedullary hypersignal to T2-weighted sequence) is also of great importance for the discussion of the indication of a gesture [16]. Although MRI is indicated as a first-line test for clinical signs of spinal cord suffering, CT may be used when there is doubt about the hard or soft nature of disc herniation. Especially since calcified disc herniation, osteophytes are part of ozone discolysis failure factors.

Classic ozone discolysis indications are disabling CBN (non-motor deficit or paresia) after conservative treatment failure and hyperalgic CBN (with conservative treatment failure). On the other hand, plegia is not part of the classic ozone discolysis indications. The realization of percutaneous ozone discolysis in this paralyzing case was imposed on us by the financial conditions of the patient that did not allow honoring conventional discectomy medical expenses. Therefore, we performed ozone discolysis while waiting for conventional surgery. Fortunately, this gesture allowed deficit full recovery. This finding was the same as for paresis cases in our study.

The high rate of patients who became asymptomatic (91.2%) observed at 3 months in our series was comparable to the x rate found in literature. Thus, in India [8], the success rate of cervical ozone discolysis was 85.36%. The mean baseline VAS score was 7.87, which became 3.09 at 1 month, 1.42 at 3 months, 1.40 at 6 months, and 1.35 at 1 year [8]. In Turkey [14], the average VAS score was 7.89 ± 1.13 before the procedure, 4.22 ± 1.62 at 2 weeks, 3.03 ± 1.66 at 6 weeks and 2.27 ± 1.25 at the end of month 6. We also noted this early improvement in pain from the first week of treatment and the gradual increase in the rate of asymptomatic patients from 61.8% at one week to 91.2% at three months without any additional intervention.

In our series no control imaging was performed because patients once the clinical signs improved are reluctant to pay for control imaging because of their modest financial means. In France [17] and Italy [18], in some cases of lumbar ozone discolysis, post-discolysis MRI had made it possible to objectify an involution of disc herniation. It seems that its efficacy in treating low back pain associated with disc herniation comes from multiple properties together: (1) the biochemical cascade of the arachidonic acid into inflammatory prostaglandins is directly interrupted by ozone; (2) it increases the concentration of oxygen in tissues suffering from hypoxemia, due to the reduced microcapillary blood flow determined by the mechanical disc compression; (3) fibroblastic cells activity is stimulated by ozone to repair the damaged disc by deposition of collagen; and (4) most important, it reduces the disc volume acting directly on the nucleus pulposus because it breaks the glycosaminoglycan chains and prevents water retention, resulting in dehydration of the disc [19]. Ant inflammatory activities, tissue oxygenation, repairing processes, and disc shrinking: all these factors contribute to relieve low back pain few after the procedure [19]. To these biochemical effects, we note a mechanical effect because the injection of ozone increases disc space with the opening of the foramina and reduced root compression. This mechanical effect most often contributes to immediate postoperative analgesia.

In addition to these very satisfactory post-discolysis results, the advantage of ozone discolysis is not only its lower cost, but also, the safety of ozone (which can be an alternative in subjects with a contraindication to general anesthesia), the fact that it is performed on an outpatient basis, the fact that it better respects anatomy (because no resection is necessary so no spinal instability aggravated or caused by this gesture even after the treatment of

several levels) and especially the fact that it can be easily taken back in case of recurrence.

Conclusion

Cervical percutaneous ozone discolysis was a good alternative to surgery in our country where the neurosurgeon is the first and only resort in case of cervicobrachiale neuralgia (CBN) by disc herniation with conservative treatment failure. Its main indications were disabling or hyperalgic CBN. The results of ozone discolysis were very satisfactory.

Surgical percutaneous ozone discolysis was a beneficial treatment for patients and surgeon. It had the advantage not only of its lower cost, but also, the harmlessness of ozone, the fact that it is performed on an outpatient basis, the fact that it better respects the anatomy and especially the fact that it can be easily taken back in case of recurrence.

A study on a larger number of cases of ozone discolysis for common CBN by disc herniation will make it possible to better specify the place of this percutaneous surgery, which from all points of view seems very interesting in the management of this condition.

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